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Presidential Documents

Title 3—

The President

Proclamation 9507 of September 30, 2016

National Breast Cancer Awareness Month, 2016

By the President of the United States of America

A Proclamation

Every year, too many Americans are touched by the pain and hardship caused by breast cancer—a disease that, among women, is not only one of the most common cancers, but also one of the leading causes of cancer-related death. During National Breast Cancer Awareness Month, we honor all those who lost their lives to breast cancer, and we recognize the courageous survivors who are still fighting it. For these individuals, and for their loved ones who give their unwavering support during the most trying times, we recommit ourselves to the essential and necessary work of forging a future free from cancer in all its forms.

Hundreds of thousands of Americans will be diagnosed with breast cancer this year, and tens of thousands will lose their battle with this disease. Although both women and men can have breast cancer, women are at higher risk. Women with a family history of breast cancer, or those who are older or obese, are also more likely to be diagnosed with breast cancer. I encourage all women to find out if they are at increased risk and to learn more about recommended screenings by speaking with their health care providers and by visiting www.Cancer.gov/Breast.

Early detection and treatment can save lives. Since I took office, I have worked to make quality, affordable health care a reality for more Americans. The Affordable Care Act has given millions of women expanded access to preventive services, including screening tests such as mammograms, with no out-of-pocket costs. Women can no longer be denied coverage because of a pre-existing condition, including a family history of breast cancer, and lifetime and annual limits on essential health benefits have been eliminated.

Critical research efforts over time have yielded great progress in how we diagnose and treat breast cancer, which has produced a steady increase in survival rates for those suffering from this disease—and it is crucial that we keep building on these successes. This year, the National Cancer Institute launched the largest study of its kind to investigate the role of genetic and biological factors in breast cancer risk among African American women, who have a higher risk of dying from breast cancer. The White House Cancer Moonshot Task Force, also launched this year, is a new national effort striving to make a decade's worth of progress in preventing, diagnosing, and treating cancer in just 5 years. And through the Precision Medicine Initiative—a bold research effort aimed at delivering disease prevention and treatment based on an individual's unique traits and genetic information—we are pursuing new oncology-focused efforts to advance personalized care through targeted cancer therapies.

This month, with bold pink ribbons displayed proudly across America, we stand in solidarity with breast cancer survivors and reaffirm our commitment to raising awareness of this disease and to advancing research efforts. Let us thank the countless advocates, medical professionals, researchers, and caregivers who dedicate their lives to fighting for a world without breast cancer, and together, let us carry out our mission to cure cancer once and for all.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2016 as National Breast Cancer Awareness Month. I encourage citizens, government agencies, private businesses, nonprofit organizations, and all other interested groups to join in activities that will increase awareness of what Americans can do to prevent breast cancer.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

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Presidential Documents

Proclamation 9508 of September 30, 2016

National Cybersecurity Awareness Month, 2016

By the President of the United States of America

A Proclamation

Technology plays an increasingly significant role in our daily lives. The rise of the Internet has brought incredible opportunity and new ways of innovating and enhancing our way of life—but with great potential also comes heightened risk to our data. Keeping cyberspace secure is a matter of national security, and in order to ensure we can reap the benefits and utility of technology while minimizing the dangers and threats it presents, we must continue to make cybersecurity a top priority. Throughout National Cybersecurity Awareness Month, we recognize the role that individuals can play in enhancing cybersecurity, and we join to raise awareness of the importance of securing our information against cyber threats.

To build on the cybersecurity efforts already underway, my Administration introduced the Cybersecurity National Action Plan earlier this year to address short-term and long-term challenges when it comes to cybersecurity. We have proposed increasing the budget for cybersecurity by more than one-third and establishing an Information Technology Modernization Fund to help retire, replace, and modernize our costly information technology legacy systems. We are also striving to invest in cybersecurity education, reform the way Government manages and responds to large-scale cyber threats, and update obsolete Federal IT systems that are vulnerable to attack.

To meet these goals, we created the position of the first-ever Federal Chief Information Security Officer to help drive cybersecurity policy, planning, and implementation across the Federal Government. We also established the Commission on Enhancing National Cybersecurity to recommend actions that can be taken over the next decade to strengthen cybersecurity in both the public and private sectors while protecting privacy. This Commission will maintain public safety and economic and national security, foster discovery and development of new technical solutions, and bolster partnerships between governments and the private sector in an effort to promote best cybersecurity practices.

Cyber threats not only pose a danger to our national security, but also have the potential to harm our financial security and undermine the privacy of millions of Americans. An important part of enhancing cybersecurity involves empowering more Americans to help themselves take proper precautions online and in their financial transactions; cybersecurity is a shared responsibility, and everyone can do their part to make smart, safe choices. The Federal Government is also doing our part through the BuySecure Initiative, which has issued more than three million more secure credit cards for Government purchases. We are also working to help give Americans earlier warning of identity crimes with free access to credit scores through their existing consumer accounts.

Through the Department of Homeland Security's ''Stop.Think.Connect.'' campaign, we are aiming to increase awareness of the simple steps people can take to strengthen their cybersecurity. The National Cyber Security Alliance, in partnership with the private sector and non-profit organizations, recently launched the ''Lock Down Your Login'' campaign to empower Americans to take control of their online accounts and add an extra layer of

security beyond just using passwords. I encourage every American to take this important step and to visit www.LockDownYourLogin.com to learn more.

Keeping America safe requires us to bolster our security online. This month, we renew our commitment to ensuring our information is more secure, our data is safer, and our families and businesses are more protected than ever before. If we work toward this goal—as individuals and as a Nation—together we can realize our full potential in the digital age.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2016 as National Cybersecurity Awareness Month. I call upon the people of the United States to recognize the importance of cybersecurity and to observe this month with activities, events, and training that will enhance our national security and resilience.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

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Presidential Documents

Proclamation 9509 of September 30, 2016

National Disability Employment Awareness Month, 2016

By the President of the United States of America

A Proclamation

Americans with disabilities are entitled to the same rights and freedoms as any other citizen—including the right to dignity and respect in the workplace. Too often in our Nation's history, individuals with disabilities have been eager to work but could not find a job, facing red tape, discrimination, or employers who assumed that disabled meant unable and refused to hire them. This month, we recognize the significant progress our country has made for those living with disabilities, and we honor the lasting contributions and diverse skills they bring to our workforce.

As a country, we must acknowledge that despite the great strides we have made in the 26 years since the passage of the Americans with Disabilities Act—a groundbreaking civil rights law aimed at eliminating discrimination and assuring equality for people with disabilities—we still have far to go to raise awareness of discriminatory obstacles that individuals with disabilities encounter in employment. Today, the labor force participation rate for Americans with disabilities is less than one-third the rate of those without a disability, and the unemployment rate is more than twice as high for individuals with disabilities. To break down more of these barriers, we must expand access to the resources and training necessary for Americans with disabilities to succeed in the workplace.

My Administration is dedicated to upholding our Nation's promise of equal opportunity for all and advancing employment for people with disabilities in every community. I am proud that the Federal Government is leading by example as a model employer, now employing more Americans with disabilities than at any time in the last 30 years. Last year, the White House hosted a Summit on Disability and Employment to share resources for employers to hire more individuals with disabilities and effective strategies for recruitment, retention, hiring, and promotion of these employees. Two years ago, through updates to Section 503 of the Rehabilitation Act, we took action to increase the representation of workers with disabilities in the Federal contractor workforce. In 2014, I signed the Workforce Innovation and Opportunity Act to help the Departments of Labor and Education build initiatives that advance employment opportunities for individuals with disabilities—and earlier this summer, we issued new regulations to provide greater and more inclusive career development and training opportunities for anyone facing barriers to employment.

This year's National Disability Employment Awareness Month theme focuses on the importance of inclusion, especially when it comes to business, opportunity, and innovation. When we diversify our workforce we create opportunities for growth and improvement—not just for those with disabilities, but for everyone. This month, let us continue striving to forge a future where workplaces are more inclusive and where employees are more accepted for who they are. And because we know that our country does best when everyone gets their fair shot, let us keep working to ensure no one is left behind or unable to pursue their dreams because of a disability.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2016 as National Disability Employment Awareness Month. I urge all Americans to embrace the talents and skills that individuals with disabilities bring to our workplaces and communities and to promote the right to equal employment opportunity for all people.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

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Presidential Documents

Proclamation 9510 of September 30, 2016

National Domestic Violence Awareness Month, 2016

By the President of the United States of America

A Proclamation

The physical and emotional scars of domestic violence can cast a long shadow. Too many individuals, regardless of age, ability, sex, sexual orientation, gender identity, circumstance, or race, face the pain and fear of domestic violence. During National Domestic Violence Awareness Month, we shine a light on this violation of the basic human right to be free from violence and abuse, pledge to ensure every victim of domestic violence knows they are not alone, and foster supportive communities that help survivors seek justice and enjoy full and healthy lives.

Over the past two decades, rates of domestic violence against females have dropped by nearly three-quarters—but there is still much work to do to build on the progress we have made. Nearly 1 in 4 women and 1 in 7 men have suffered from domestic violence by an intimate partner. All people deserve to feel safe with loved ones, and my Administration is committed to eliminating this scourge and supporting survivors' healing—and we must ensure that survivors and their families have access to the resources, care, and support they need to do so.

My Administration is dedicated to ensuring that all people feel safe in all aspects of their lives, which is why I proposed significant funding for responding to domestic violence in my most recent budget proposal. We have also championed legislative action like the Family Violence Prevention and Services Act, and the Affordable Care Act—which ensures that most health plans cover domestic violence screening and counseling services at no additional cost. And the Violence Against Women Act, which was reauthorized in 2013, has enhanced and expanded protections to Native Americans, immigrants, lesbian, gay, bisexual, and transgender individuals, and victims who reside in public housing.

This is progress we must continue to invest in and carry forward. Earlier this year, I announced a series of commonsense steps my Administration is taking to reduce gun violence, including work to renew our domestic violence outreach efforts. Building on the work of our Police Data Initiative, the White House is promoting smart approaches to collecting data on domestic violence offenses that balance transparency and accountability with victim safety and privacy. And victim safety should also be a priority in the workplace—a truth that extends to the Federal Government. That is why I directed all Federal agencies to adopt domestic violence workplace policies and encouraged employers to do the same.

Our agencies have taken many critical actions to advance this cause. For example, the Department of Justice has invested millions of dollars in new initiatives to prevent domestic violence homicides, urge law enforcement agencies to identify and prevent gender bias when responding to domestic violence and sexual assault, and expand services to underserved victims. And the Department of Housing and Urban Development recently issued guidance to prevent housing discrimination against survivors of domestic violence.

Vice President Joe Biden's leadership has helped guide our progress and worked to change our national culture—which too often tolerates and condones domestic violence. We are challenging harmful stereotypes associated with victims of domestic violence and striving to bring the practice of victim-blaming to an end. We must continue to recognize survivors who experience disproportionate rates of domestic violence, and who have been placed at the margins for generations, including women of color, Native Americans, individuals with disabilities, members of the LGBT community, immigrants, and older adults. Along these lines, we also joined with Canada and Mexico to create the North American Working Group on Violence against Indigenous Women and Girls, working together to enhance responses to violent crimes against indigenous women and girls in North America.

Our Nation's character is tested whenever this injustice is tolerated. When anyone is targeted by someone they place their trust in, we have a responsibility to speak up. We all have a role to play in building a bright and safe future for each other and for future generations. This month, we recommit to standing with survivors of domestic violence and to doing our utmost to extend hope and healing to all who need it. If you or someone you know needs assistance, I encourage you to reach out to the National Domestic Violence Hotline, which recently engaged in its 4 millionth conversation with victims and survivors of domestic violence, by calling 1–800–799–SAFE, or visiting www.TheHotline.org.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2016 as National Domestic Violence Awareness Month. I call on all Americans to speak out against domestic violence and support local efforts to assist victims of these crimes in finding the help and healing they need.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

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Presidential Documents

Proclamation 9511 of September 30, 2016

National Energy Action Month, 2016

By the President of the United States of America

A Proclamation

The sustainability of our country and our world in the 21st century rests on our ability to address our shared energy challenges and to encourage diverse, clean, and efficient energy production. During National Energy Action Month, we rededicate ourselves to securing a more prosperous and energy-independent future. As climate change continues to threaten our planet, we must join together to reduce our carbon emissions, protect our environment, and leave behind a cleaner and more resilient world for generations to come.

Today, America is less reliant on foreign oil than at any point in the previous four decades. To build on this progress, we are implementing new fuel efficiency standards for medium- and heavy-duty vehicles that are projected to significantly reduce diesel consumption. We are also increasing the energy efficiency of our buildings and appliances and modernizing our energy infrastructure as we experience a rapid transformation in the way power is generated and used across our country.

To ensure our energy security for generations, the United States is partnering with Canada and Mexico to pursue regional energy security and combat climate change. Earlier this year at the North American Leaders Summit, we set an historic goal of achieving 50 percent clean power generation across our continent by 2025. These efforts will bolster a transition to clean energy sources that increase economic competitiveness and strengthen growing industries while supporting hundreds of thousands of new jobs. Our solar industry is creating jobs 12 times faster than the rest of the economy, and wind generation now supports tens of thousands of American jobs. Additionally, we are working to diversify our energy portfolio to include sources of zero emissions power like nuclear and hydropower; expand our supply of affordable, reliable, and efficient energy sources; and make it easier for every American to access cleaner forms of energy.

In response to the devastating consequences of our changing climate, we are embracing our responsibility to achieve a low-carbon future. To do our part, we are on track to reach the 2020 emissions reductions goals I set when I first took office, and we are pursuing even greater cuts for 2025. Last year, we joined nearly 200 countries for the announcement of the most ambitious climate agreement in history, and in September we formally joined the Paris Agreement with China. As we embolden the world to take steps that will dramatically reduce global carbon pollution, we are leading by example—our levels of carbon pollution remain at historic lows. We must continue demonstrating that a country can simultaneously strive for a cleaner environment and a stronger economy.

Despite this progress, there is much work to do to realize the clean energy economy of tomorrow. Last year, in partnership with 19 other countries, we launched Mission Innovation to accelerate clean energy innovation around the world. Through this initiative, 20 countries and the European Union committed to seeking to double public funding for clean energy research and development to $30 billion over 5 years. By doubling our proposed Federal investment in clean energy, we will enable our brightest scientists,

engineers, and entrepreneurs to create and advance clean energy technologies that will protect our environment, increase our energy security, and create more jobs across our country.

Although the difficulties that lie ahead are large, the stakes are too great for inaction. Our children and grandchildren are relying on our ability to rise to these challenges and accomplish what is required of us—including advancing clean, renewable, and independent sources of energy. Throughout National Energy Action Month, let us pledge to reduce our carbon footprint and minimize our energy consumption. Let us strive to continue fighting for a cleaner, stronger, and more secure future for our fellow Americans and for all of humanity.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2016 as National Energy Action Month. I call upon the citizens of the United States to recognize this month by working together to achieve greater energy security, a more robust economy, and a healthier environment for our children.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–24367
Filed 10–5–16; 8:45 am]
Billing code 3295–F7–P

Presidential Documents

Proclamation 9512 of September 30, 2016

National Youth Justice Awareness Month, 2016

By the President of the United States of America

A Proclamation

The essential promise that we make to our young people—that where they start must not determine how far they can go—is part of what makes America exceptional. It is our shared responsibility to ensure all children are given a fair shot at life, including a quality education and equal opportunities to pursue their dreams. Too often in America, young people are not afforded a second chance after having made a mistake or poor decision—the kind of chance some of their peers receive under more forgiving environments. Many of these young people lack institutional or family support and live in distressed communities. Others may have experienced trauma and violence or may struggle with disabilities, mental health issues, or substance use disorders. As a society, we must strive to reach these children earlier in life and modernize our juvenile and criminal justice systems to hold youth accountable for their actions without consigning them to a life on the margins. During National Youth Justice Awareness Month, we reaffirm our commitment to helping children of every background become successful and engaged citizens.

While the number of juvenile arrests have fallen sharply over the past decade, roughly 1 million juvenile arrests were made in 2014. An overwhelming majority of these arrests were for non-violent crimes, and nearly three-quarters of those arrested were male. Children of color, particularly black and Hispanic males and Native American youth, continue to be over-represented across all levels of the juvenile justice system. Unfortunately, far too many youth become involved with the adult criminal justice system each year—including in several States where 17-year-olds are prosecuted as adults regardless of their crime, and two where 16-year-olds are as well. Children in the adult system have less access to rehabilitative services and often face higher recidivism and suicide rates. Some States have recently raised the age so that 16- and 17-year-olds are not unnecessarily tried in adult courts, and many are reforming sentencing laws and expanding access to age-appropriate transition services upon reentry.

Even for those youth who were never convicted or otherwise found guilty, simply having had contact with our justice system can lead to lifelong barriers and an increased likelihood of ending up in a cycle of incarceration. To help break this cycle, my Administration increased funding for expunging juvenile records and took steps to ensure young people in juvenile and adult justice facilities can receive Pell Grants to pursue a quality education. The White House launched the Fair Chance Pledge to highlight employers and institutions of higher education that have committed to reducing barriers that justice-involved youth often face in accessing employment, training, and education. To build on these efforts, the Congress must reauthorize the Juvenile Justice and Delinquency Prevention Act (JJDPA) to increase protections for youth and limit the number of minors held in adult jails and prisons. Reauthorizing the JJDPA will promote evidence-based practices, quality education, and trauma-informed care for incarcerated youth, while reducing punishments for things such as breaking curfew and truancy.

We have also seen too many of our youth held in solitary confinement while incarcerated, which can lead to devastating, long-term psychological consequences. Earlier this year, my Administration took steps to implement reforms that include banning this harmful practice for juveniles under the custody of the Federal Bureau of Prisons. We must ensure that young people have quality legal representation throughout every stage of the legal process as well as age-appropriate and rehabilitative sentencing and placements. The financial costs of the juvenile court system can be debilitating and can unfairly penalize children from poor families—by reducing the fees and fines imposed on youth, we can avoid pushing families into debt and decrease this disproportionate burden.

To meet these goals, we must engage young people before they find themselves locked into a path from which they cannot escape. The Departments of Justice and Education created the Supportive School Discipline Initiative to incentivize positive school climates and rethink discipline policies to foster safer and more supportive learning environments. They are also working to assist States, schools, and law enforcement partners in assessing the proper role of school resource officers and campus law enforcement professionals. The Departments of Justice and Health and Human Services released a joint policy statement against the use of suspension and expulsion in preschool settings—which disproportionately affect children of color. As part of the Office of Juvenile Justice and Delinquency Prevention's Smart on Juvenile Justice initiative, we are providing services such as job training and substance use disorder treatment and counseling for youth in juvenile facilities, and we are expanding the use of effective community-based alternatives to youth detention. We are also screening youth for exposure to trauma that can put them at greater risk of entering the juvenile justice system. And through the My Brother's Keeper initiative, we are working to address persistent opportunity gaps and ensure all young people can reach their full potential—including by helping them get a healthy start in life, enter school ready to learn, and successfully enter the workforce.

When we invest in our children and redirect young people who have made misguided decisions, we can reduce our over-reliance on the juvenile and criminal justice systems and build stronger pathways to opportunity. In addition, for every dollar we put into high-quality early childhood education, we save at least twice that down the road in reduced crime. That is why my Administration has sought to expand high-quality early education by increasing funding for programs like Head Start and investing in preschool, child care, and evidence-based home visiting. Investing in our communities and our kids makes sense, and if we recognize that every child deserves to remain connected to their families and communities, we can ensure youth who come in contact with the law can have a chance at a brighter future.

This month, we come together to ensure all young people are supported, nurtured, and provided an opportunity to succeed. We must make sure youth in every community and from every walk of life can be known for more than their worst mistakes. With enhanced possibilities, a sense of optimism, and an open mind, they can all thrive and live up to the full measure of their promise.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2016 as National Youth Justice Awareness Month. I call upon all Americans to observe this month by taking action to support our youth and by participating in appropriate ceremonies, activities, and programs in their communities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–24368
Filed 10–5–16; 8:45 am]
Billing code 3295–F7–P

Presidential Documents

Proclamation 9513 of September 30, 2016

National Community Policing Week, 2016

By the President of the United States of America

A Proclamation

Police officers are essential members of our communities—maintaining our way of life depends on their dedicated efforts to keep us safe. These officers hold significant civic and law enforcement responsibilities and put their lives at risk to protect us each day, at times facing some of the most adverse circumstances imaginable. The overwhelming majority of police officers are fair, dedicated, and honest public servants who strive daily to cultivate and sustain positive relationships with the communities they serve and protect. As recent tragedies have illustrated, however, it is clear that there are still too many places in America where these relationships are strained and where officers and community members have struggled to build and maintain trust.

During National Community Policing Week, we reaffirm our commitment to supporting and advancing the practice of community policing and to fortifying the bonds between police officers and communities. Community policing recognizes that law enforcement cannot solve public safety problems alone and encourages interactive partnerships with relevant stakeholders—including community groups, nonprofits, faith-based organizations, and businesses. This active collaboration can improve public trust and fortify relationships, not only advancing public safety, but also deepening social connectivity and creating lasting solutions to challenging problems we face every day.

The underlying tensions that sometimes exist between law enforcement officers and communities span decades and reflect a breadth of social and cultural challenges, including racial and socioeconomic disparities. Through meaningful efforts to strengthen community policing, we can meet these challenges, improve these vital relationships, and make real and lasting progress. Together, we can take constructive steps to support our women and men in uniform while instilling confidence in the fairness of the justice system for everybody and ensuring that law enforcement officers discharge their duties impartially.

A critical part of enhancing trust is making certain that when an incident occurs, the public is confident that an investigation is fair and effective—both for the officer and for the families of those who have been affected. We must also work with law enforcement on training, hiring, and recruiting techniques and provide support and proper resources as they deal with the challenges of the job. In 2015, I announced a Task Force on 21st Century Policing to bring together community leaders and law enforcement to provide recommendations to help us build the kind of trust we need. In the time since the Task Force issued a report of their findings, we have seen progress with respect to data gathering, training, transparency, and community outreach—and communities across America are working to implement these recommendations. We must also recognize that we cannot keep expecting police to solve the issues we fail to address as a society, including poverty, substandard schools, inadequate job opportunities, and lack of care for mental illnesses or substance use disorders; doing so contributes to unrest in communities and exacerbates tensions.

My Administration has worked to bridge divides and bolster community policing efforts across our country. In 2014, the Department of Justice (DOJ) launched the National Initiative for Building Community Trust and Justice to invest in training, evidence-based strategies, and research to help reduce implicit bias and enhance procedural justice and reconciliation. The DOJ has provided additional resources to the Office of Community Oriented Policing Services for hiring police officers across America and advancing 21st-century policing efforts. We are also continuing to provide millions of dollars in grants to agencies that demonstrate robust community policing initiatives. Last year, the White House and the DOJ launched the Police Data Initiative to encourage law enforcement, technologists, and researchers to use data to increase transparency and strengthen accountability between community members and police. And this summer, we launched the Data-Driven Justice Initiative to equip law enforcement officers with the tools they need to safely and effectively divert low-level offenders with mental illnesses out of the criminal justice system. The Federal Government must continue to partner with State and local leaders, as well as the law enforcement community, to expand best practices that increase trust and public safety.

Every American has the power to make change in their communities. By working together to improve law enforcement practices and ensure we give both police officers and community members the respect they deserve, we can fulfill this important endeavor. This week, let us rededicate ourselves to building a future in which police officers are honored for their sacrifices and supported by their communities and in which members of those communities can truly feel they are being served fairly and justly by our women and men in blue.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2 through October 8, 2016, as National Community Policing Week. I call upon law enforcement agencies, elected officials, and all Americans to observe this week by recognizing ways to improve public safety, rebuild trust, and strengthen community relationships.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–24374

Filed 10–5–16; 8:45 am]

Billing code 3295–F7–P

Rules and Regulations

Federal Register
Vol. 81, No. 194
Thursday, October 6, 2016

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2016–0394; FRL–9953–50–Region 10]

Approval and Promulgation of Implementation Plans; Washington: Updates to Incorporation by Reference and Miscellaneous Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving State Implementation Plan revisions submitted by the Washington State Department of Ecology (Ecology) on July 11, 2016. The revisions update the incorporation by reference of federal provisions cited in Ecology's general air quality regulations. The revisions also reflect changes to the primary and secondary National Ambient Air Quality Standards (NAAQS) for ozone, promulgated since Ecology's last update. Ecology also made minor corrections to typographical errors and non-substantive edits for clarity, such as standardizing the citation format.

DATES: This final rule is effective November 7, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2016–0394. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and is publicly available only in hard copy form. Publicly available docket materials are available at *http://www.regulations.gov* or at EPA Region 10, Office of Air and Waste, 1200 Sixth Avenue, Seattle, Washington 98101. The EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, Air Planning Unit, Office of Air and Waste (OAW–150), Environmental Protection Agency, Region 10, 1200 Sixth Ave., Suite 900, Seattle, WA 98101; telephone number: (206) 553–0256; email address: *hunt.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background Information
II. Final Action
III. Incorporation by Reference
IV. Statutory and Executive Orders Review

I. Background Information

On August 12, 2016, the EPA proposed to approve revisions to Ecology's general air quality regulations contained in Chapter 173–400 Washington Administrative Code (WAC) and the State ambient air quality standards contained in Chapter 173–476 WAC (81 FR 53362). An explanation of the Clean Air Act requirements, a detailed analysis of the revisions, and the EPA's reasons for proposing approval were provided in the notice of proposed rulemaking, and will not be restated here. The public comment period for this proposed rule ended on September 12, 2016. The EPA received no comments on the proposal.

II. Final Action

The EPA is approving, and incorporating by reference, the submitted revisions to Chapters 173–400 and 173–476 WAC set forth below as amendments to 40 CFR part 52. We are also approving, but not incorporating by reference, the revised version of WAC 173–400–260 *Conflict of Interest,* state effective July 1, 2016. Consistent with prior actions on the Washington SIP, the EPA reviews and approves state and local clean air agency submissions to ensure they provide adequate enforcement authority and other general authority to implement and enforce the SIP. However, regulations describing such agency enforcement and other general authority are typically not incorporated by reference so as to avoid potential conflict with the EPA's independent authorities.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference as described in the amendments to 40 CFR part 52 set forth below. These materials have been approved by the EPA for inclusion in the State Implementation Plan, have been incorporated by reference by the EPA into that plan, are fully federally-enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[1] The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and/or at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Orders Review

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a

[1] 62 FR 27968 (May 22, 1997).

substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land in Washington, except as specifically noted below, and is also not approved to apply in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). Washington's SIP is approved to apply on non-trust land within the exterior boundaries of the Puyallup Indian Reservation, also known as the 1873 Survey Area. Under the Puyallup Tribe of Indians Settlement Act of 1989, 25 U.S.C. 1773, Congress explicitly provided state and local agencies in Washington authority over activities on non-trust lands within the 1873 Survey Area. Consistent with EPA policy, the EPA provided a consultation opportunity to the Puyallup Tribe in a letter dated July 13, 2016.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 5, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: September 19, 2016.

Dennis J. McLerran,

Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart WW—Washington

■ 2. In § 52.2470:

■ a. Amend paragraph (c):

■ i. ''Table 1—Regulations Approved Statewide'', by revising entries 173–476–020, 173–476–150, and 173–476–900.

■ ii. ''Table 2—Additional Regulations Approved for Washington Department of Ecology (Ecology) Direct Jurisdiction'', by adding entry 173–400–025 in numerical order, and revising entries 173–400–040, 173–400–050, 173–400–060, 173–400–070, 173–400–105, 173–400–111, 173–400–116, 173–400–171, 173–400–710, 173–400–720, 173–400–730, 173–400–740, 173–400–810, 173–400–830, 173–400–840, and 173–400–850.

■ iii. ''Table 4—Additional Regulations Approved for the Benton Clean Air Agency (BCAA) Jurisdiction'', by adding entry 173–400–025 in numerical order, and revising entries 173–400–040, 173–400–050, 173–400–060, 173–400–070, 173–400–105, 173–400–111, 173–400–171, 173–400–810, 173–400–830, 173–400–840, and 173–400–850.

■ b. Amend paragraph (e), ''Table 1—Approved but Not Incorporated by Reference Regulations'', by revising entry 173–400–260.

The additions and revisions read as follows:

§ 52.2470 Identification of plan.

* * * * *

(c) * * *

TABLE 1—REGULATIONS APPROVED STATEWIDE

[Not applicable in Indian reservations (excluding non-trust land within the exterior boundaries of the Puyallup Indian Reservation) and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction]

State citation	Title/Subject	State effective date	EPA Approval date	Explanations
*	*	*	*	*
Washington Administrative Code, Chapter 173–476—Ambient Air Quality Standards				
*	*	*	*	*
173–476–020	Applicability	07/01/16	10/06/16, [Insert **Federal Register** citation].	
*	*	*	*	*
173–476–150	Ambient Air Quality Standard for Ozone.	07/01/16	10/06/16, [Insert **Federal Register** citation].	
*	*	*	*	*
173–476–900	Table of Standards	07/01/16	10/06/16, [Insert **Federal Register** citation].	
*	*	*	*	*

TABLE 2—ADDITIONAL REGULATIONS APPROVED FOR WASHINGTON DEPARTMENT OF ECOLOGY (ECOLOGY) DIRECT JURISDICTION

[Applicable in Adams, Asotin, Chelan, Columbia, Douglas, Ferry, Franklin, Garfield, Grant, Kittitas, Klickitat, Lincoln, Okanogan, Pend Oreille, San Juan, Stevens, Walla Walla, and Whitman counties, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction, Indian reservations (excluding non-trust land within the exterior boundaries of the Puyallup Indian Reservation), and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. These regulations also apply statewide for facilities subject to the applicability sections of WAC 173–400–700, 173–405–012, 173–410–012, and 173–415–012]

State citation	Title/Subject	State effective date	EPA Approval date	Explanations
Washington Administrative Code, Chapter 173–400—General Regulations for Air Pollution Sources				
*	*	*	*	*
173–400–025	Adoption of Federal Rules	07/01/16	10/06/16, [Insert **Federal Register** citation].	
*	*	*	*	*
173–400–040	General Standards for Maximum Emissions.	07/01/16	10/06/16, [Insert **Federal Register** citation].	Except: 173–400–040(2)(c); 173–400–040(2)(d); 173–400–040(3); 173–400–040(5); 173–400–040(7), second paragraph.
173–400–050	Emission Standards for Combustion and Incineration Units.	07/01/16	10/06/16, [Insert **Federal Register** citation].	Except: 173–400–050(2); 173–400–050(4); 173–400–050(5); 173–400–050(6).
173–400–060	Emission Standards for General Process Units.	07/01/16	10/06/16, [Insert **Federal Register** citation].	
173–400–070	Emission Standards for Certain Source Categories.	07/01/16	10/06/16, [Insert **Federal Register** citation].	Except: 173–400–070(7); 173–400–070(8).
*	*	*	*	*
173–400–105	Records, Monitoring, and Reporting.	07/01/16	10/06/16, [Insert **Federal Register** citation].	
*	*	*	*	*
173–400–111	Processing Notice of Construction Applications for Sources, Stationary Sources and Portable Sources.	07/01/16	10/06/16, [Insert **Federal Register** citation].	Except: 173–400–111(3)(h); The part of 173–400–111(8)(a)(v) that says, • "and 173–460–040,"; 173–400–111(9).
*	*	*	*	*
173–400–116	Increment Protection	07/01/16	10/06/16, [Insert **Federal Register** citation].	

TABLE 2—ADDITIONAL REGULATIONS APPROVED FOR WASHINGTON DEPARTMENT OF ECOLOGY (ECOLOGY) DIRECT JURISDICTION—Continued

[Applicable in Adams, Asotin, Chelan, Columbia, Douglas, Ferry, Franklin, Garfield, Grant, Kittitas, Klickitat, Lincoln, Okanogan, Pend Oreille, San Juan, Stevens, Walla Walla, and Whitman counties, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction, Indian reservations (excluding non-trust land within the exterior boundaries of the Puyallup Indian Reservation), and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. These regulations also apply statewide for facilities subject to the applicability sections of WAC 173–400–700, 173–405–012, 173–410–012, and 173–415–012]

State citation	Title/Subject	State effective date	EPA Approval date	Explanations
*	* *	*	*	* *
173–400–171	Public Notice and Opportunity for Public Comment.	07/01/16	10/06/16, [Insert **Federal Register** citation].	Except: The part of 173–400–171(3)(b) that says, • "or any increase in emissions of a toxic air pollutant above the acceptable source impact level for that toxic air pollutant as regulated under chapter 173–460 WAC"; 173–400–171(12).
*	* *	*	*	* *
173–400–710	Definitions	07/01/16	10/06/16, [Insert **Federal Register** citation].	
173–400–720	Prevention of Significant Deterioration (PSD).	07/01/16	10/06/16, [Insert Federal Register citation].	Except: 173–400–720(4)(a)(i through iv) and 173–400–720(4)(b)(iii)(C).
173–400–730	Prevention of Significant Deterioration.	07/01/16	10/06/16, [Insert **Federal Register** citation].	
	Application Processing Procedures.			
173–400–740	PSD Permitting Public Involvement.	07/01/16	10/06/16, [Insert **Federal Register** citation].	
	Requirements			
*	* *	*	*	* *
173–400–810	Major Stationary Source and Major Modification Definitions.	07/01/16	10/06/16, [Insert **Federal Register** citation].	
*	* *	*	*	* *
173–400–830	Permitting Requirements	07/01/16	10/06/16, [Insert **Federal Register** citation].	
173–400–840	Emission Offset Requirements	07/01/16	10/06/16, [Insert **Federal Register** citation].	
173–400–850	Actual Emissions Plantwide Applicability.	07/01/16	10/06/16, [Insert **Federal Register** citation].	
	Limitation (PAL)			
*	* *	*	*	* *

* * * * *

TABLE 4—ADDITIONAL REGULATIONS APPROVED FOR THE BENTON CLEAN AIR AGENCY (BCAA) JURISDICTION

[Applicable in Benton County, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction, Indian reservations and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and facilities subject to the applicability sections of WAC 173–400–700, 173–405–012, 173–410–012, and 173–415–012]

State/local citation	Title/Subject	State/local effective date	EPA Approval date	Explanations
*	* *	*	*	* *
Washington Department of Ecology Regulations				
Washington Administrative Code, Chapter 173–400—General Regulations for Air Pollution Sources				
173–400–025	Adoption of Federal Rules	07/01/16	10/06/16, [Insert **Federal Register** citation].	

TABLE 4—ADDITIONAL REGULATIONS APPROVED FOR THE BENTON CLEAN AIR AGENCY (BCAA) JURISDICTION—Continued

[Applicable in Benton County, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction, Indian reservations and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and facilities subject to the applicability sections of WAC 173–400–700, 173–405–012, 173–410–012, and 173–415–012]

State/local citation	Title/Subject	State/local effective date	EPA Approval date	Explanations
*	*	*	*	*
173–400–040	General Standards for Maximum Emissions.	07/01/16	10/06/16, [Insert **Federal Register** citation].	Except: 173–400–040(2)(c); 173–400–040(2)(d); 173–400–040(3); 173–400–040(4); 173–400–040(5); 173–400–040(7), second paragraph; 173–400–040(9)(a); 173–400–040(9)(b).
173–400–050	Emission Standards for Combustion and Incineration Units.	07/01/16	10/06/16, [Insert **Federal Register** citation].	Except: 173–400–050(2); 173–400–050(4); 173–400–050(5); 173–400–050(6).
173–400–060	Emission Standards for General Process Units.	07/01/16	10/06/16, [Insert **Federal Register** citation].	
173–400–070	Emission Standards for Certain Source Categories.	07/01/16	10/06/16, [Insert **Federal Register** citation].	Except: 173–400–070(7); 173–400–070(8).
*	*	*	*	*
173–400–105	Records, Monitoring and Reporting.	07/01/16	10/06/16, [Insert **Federal Register** citation].	
*	*	*	*	*
173–400–111	Processing Notice of Construction Applications for Sources, Stationary Sources and Portable Sources.	07/01/16	10/06/16, [Insert **Federal Register** citation].	Except: 173–400–111(3)(h);— The part of 173–400–111(8)(a)(v) that says, "and 173–460–040,"; 173–400–111(9).
*	*	*	*	*
173–400–171	Public Notice and Opportunity for Public Comment.	07/01/16	10/06/16, [Insert **Federal Register** citation].	Except:— The part of 173–400–171(3)(b) that says, "or any increase in emissions of a toxic air pollutant above the acceptable source impact level for that toxic air pollutant as regulated under chapter 173–460 WAC"; 173–400–171(12).
*	*	*	*	*
173–400–810	Major Stationary Source and Major Modification Definitions.	07/01/16	10/06/16, [Insert **Federal Register** citation].	
*	*	*	*	*
173–400–830	Permitting Requirements	07/01/16	10/06/16, [Insert **Federal Register** citation].	
173–400–840	Emission Offset Requirements	07/01/16	10/06/16, [Insert **Federal Register** citation].	
173–400–850	Actual Emissions Plantwide Applicability Limitation (PAL).	07/01/16	10/06/16, [Insert **Federal Register** citation].	
*	*	*	*	*

* * * * * (e) * * *

TABLE 1—APPROVED BUT NOT INCORPORATED BY REFERENCE REGULATIONS

State/local citation	Title/Subject	State/local effective date	EPA Approval date	Explanations
Washington Department of Ecology Regulations				
*	*	*	*	*
173–400–260	Conflict of Interest	07/01/16	10/06/16, [Insert **Federal Register** citation].	
*	*	*	*	*

* * * * *

[FR Doc. 2016–23862 Filed 10–5–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2016–0240; FRL–9950–74–Region 9]

Approval and Limited Approval and Limited Disapproval of Air Quality Implementation Plans; California; Northern Sonoma County Air Pollution Control District; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing action on five permitting rules submitted as a revision to the Northern Sonoma County Air Pollution Control District (NSCAPCD or District) portion of the applicable state implementation plan (SIP) for the State of California pursuant to requirements under the Clean Air Act (CAA or Act). We are finalizing a limited approval and limited disapproval of two rules; we are finalizing approval of the remaining three permitting rules; and we are deleting three rules. The amended rules govern the issuance of permits for stationary sources, including review and permitting of minor sources, major sources and major modifications under part C of title I of the Act. The limited disapproval actions trigger an obligation for EPA to promulgate a Federal Implementation Plan (FIP) for the specific New Source Review (NSR) program deficiencies unless California submits and we approve SIP revisions that correct the deficiencies within two years of the final action.

DATES: This rule will be effective on November 7, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket No. EPA–R09–OAR–2016–0240. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Laura Yannayon, by phone: (415) 972–3534 or by email at *yannayon.laura@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, the terms ''we,'' ''us,'' and ''our'' refer to EPA.

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I. Proposed Action
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I. Proposed Action

On May 19, 2016 (81 FR 31567), the EPA proposed a limited approval and limited disapproval (LA/LD) or a full approval (as noted in the table) of the following rules that were submitted for incorporation into the Northern Sonoma County portion of the California SIP.

TABLE 1—SUBMITTED NSR RULES

Rule No.	Rule title	Amended	Submitted	Proposed action
130	Definitions	11/14/14	12/11/14	LA/LD.
200	Permit Requirements	11/14/14	12/11/14	Full Approval.
220	New Source Review	11/14/14	12/11/14	LA/LD.
230	Action on Applications	11/14/14	12/11/14	Full Approval.
240	Permit to Operate	2/22/84	10/16/85	Full Approval.

We proposed a full approval of Rules 200, 230 and 240 because we determined that these rules improve the SIP and are consistent with the relevant CAA requirements. We proposed a limited approval of Rules 130 and 220 because we determined that these rules improve the SIP and are largely consistent with the relevant CAA requirements. We simultaneously proposed a limited disapproval of Rules 130 and 220 because some rule provisions conflict with section 110 and part C of the Act. These provisions include the following:

A. The definition of Significant in Rule 130 does not include lead as a pollutant or provide a significant emission rate. The rule also does not provide a public notice threshold for lead.

B. Rule 220 does not contain any provisions specifying that required air quality modeling shall be based on the applicable models, databases, and other requirements specified in Part 51 Appendix W; therefore, the requirements of 40 CFR 51.160(f) and 51.166(l) have not been meet.

C. The text in Rule 220, Subsection (b)(3) contains a significant typographical error (the word ''not'' is missing) concerning the requirements pertaining to stack height.

D. The requirements of 40 CFR 51.166(r)(1) and (2), regarding sources obligations, have not been met because the rule does not include the specific language required by these provisions.

We also proposed to remove existing Rules 10, 12 and 18 from the SIP, as the submitted rules replaced the content of these rules. Our proposed action contains more information on the basis for this rulemaking and on our evaluation of the submittal.

II. EPA Action

No comments were submitted. Therefore, as authorized in sections 110(k)(3) and 301(a) of the Act, the EPA is finalizing a limited approval of Rules 130 and 220 and a full approval of Rules 200, 230 and 240. We are also deleting Rules 10, 12 and 18 from the Northern Sonoma County portion of the California SIP. This action incorporates the submitted rules into the Northern Sonoma County portion of the California SIP, including those provisions identified as deficient. As authorized under section 110(k)(3) and 301(a), the EPA is simultaneously finalizing a limited disapproval of Rules 130 and 220.

As a result, the EPA must promulgate a federal implementation plan under section 110(c) unless we approve subsequent SIP revisions that correct the rule deficiencies within 24 months.

In addition, because we are finalizing our proposed action, the California Infrastructure SIP deficiencies identified in our April 2016 (81 FR 18766) rulemaking with respect to Northern Sonoma County APCD for the 1997 and 2006 $PM_{2.5}$ NAAQS are remedied. Therefore we are updating the Northern Sonoma County portion of the California SIP accordingly.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the NSCAPCD rules described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and in hard copy at the U.S. Environmental Protection Agency, Region IX (Air-3), 75 Hawthorne Street, San Francisco, CA 94105–3901.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 5, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be

challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Carbon monoxide, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides, Volatile organic compounds, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 5, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(6)(xvi)(D), (c)(35)(xvi)(D), (c)(42)(xxi)(B), (c)(50)(v)(C), (c)(124)(ix)(D), (c)(156)(vi)(B), (c)(162)(i)(B), (c)(164)(i)(B)(*4*) and (*5*), (c)(165)(i)(A)(*2*), (c)(254)(i)(B)(*2*), (c)(385)(i)(B)(*2*), and (c)(480)(i)(A) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(6) * * *

(xvi) * * *

(D) Previously approved on September 22, 1972 in paragraph (c)(6) of this section and now deleted without replacement, Rules 10, 12 and 18.

* * * * *

(35) * * *

(xvi) * * *

(D) Previously approved on August 16, 1978 in paragraph (c)(35)(xvi)(B) of this section and now deleted without replacement, Rule 130.

* * * * *

(42) * * *

(xxi) * * *

(B) Previously approved on December 21, 1978 in paragraph (c)(42)(xxi)(A) of this section and now deleted with replacement in paragraph (c)(164)(i)(B)(*4*) of this section, Rule 240(e).

* * * * *

(50) * * *

(v) * * *

(C) Previously approved on October 31, 1980 in paragraph (c)(50)(v)(A) of this section and now deleted with replacement in paragraph (c)(164)(i)(B)(*4*) of this section, Rule 240.

* * * * *

(124) * * *

(ix) * * *

(D) Previously approved on July 31, 1985 in paragraph (c)(124)(ix)(B) of this section and now deleted without replacement, Rule 130 (introductory text, b1, n1, p5, and s2), and now deleted with replacement in paragraphs (c)(481)(i)(A)(*3*) and (*4*) of this section, Rules 220(c) and 230.

* * * * *

(156) * * *

(vi) * * *

(B) Previously approved on July 31, 1985 in paragraph (c)(156)(vi)(A) of this section and now deleted without replacement, Rule 130 (b2, m1, p3, p3a, and s7), and now deleted with replacement in paragraph (c)(481)(i)(A)(*3*) of this section, Chapter II, 220(B).

* * * * *

(162) * * *

(i) * * *

(B) Previously approved on July 31, 1985 in paragraph (c)(162)(i)(A) of this section and now deleted with replacement in paragraph (c)(481)(i)(A)(*3*) of this section, Rule 220(a).

* * * * *

(164) * * *

(i) * * *

(B) * * *

(*4*) Rule 240, ''Permit to Operate,'' adopted on February 22, 1984.

(*5*) Previously approved on April 17, 1987 in paragraph (c)(164)(i)(B)(*1*) of this section and now deleted without replacement, Rule 130 (d1 and s5), and now deleted with replacement in paragraph (c)(481)(i)(A)(*2*) of this section, Rule 200(a).

* * * * *

(165) * * *

(i) * * *

(A) * * *

(*2*) Previously approved on April 17, 1987 in paragraph (c)(165)(i)(A)(*1*) of this section and now deleted without replacement, Rule 130 (s4).

* * * * *

(254) * * *

(i) * * *

(B) * * *

(*2*) Previously approved on February 9, 1999 in paragraph (c)(254)(i)(B)(*1*) of this section and now deleted without replacement, Rule 130.

* * * * *

(385) * * *

(i) * * *

(B) * * *

(*2*) Previously approved on May 6, 2011 in paragraph (c)(385)(i)(B)(*1*) of this section and now deleted with replacement in paragraph (c)(481)(i)(A)(*1*) of this section, Rule 130, ''Definitions,'' amended December 14, 2010.

* * * * *

(480) New and amended regulations for the following AQMD was submitted on December 11, 2014 by the Governor's Designee.

(i) Incorporation by Reference.

(A) Northern Sonoma County Air Pollution Control District.

(*1*) Rule 130, ''Definitions,'' adopted on November 14, 2014.

(*2*) Rule 200, ''Permit Requirements,'' adopted on November 14, 2014.

(*3*) Rule 220, ''New Source Review,'' adopted on November 14, 2014.

(*4*) Rule 230, ''Action on Applications,'' adopted on November 14, 2014.

§ 52.223 [Amended]

■ 3. Section 52.223 is amended by removing and reserving paragraphs (i)(4), (j)(3), (k)(3), (l)(4), (m)(3), (n)(3), and (o)(3).

§ 52.233 [Amended]

■ 4. Section 52.233 is amended by removing and reserving paragraph (d)(17).

■ 5. Section 52.270 is amended by revising the first sentence in paragraph (b)(4) to read as follows:

§ 52.270 Significant deterioration of air quality.

* * * * *

(b) * * *

(4) The PSD program for Northern Sonoma County Air Pollution Control District, as incorporated by reference in § 52.220(c)(481) is approved under Part C, Subpart 1, of the Clean Air Act.

* * *

* * * * *

§ 52.283 [Amended]

■ 6. Section 52.283 is amended by removing and reserving paragraphs (c)(1)(iii), (d)(1)(iii), (e)(2)(iii), (f)(2)(iii), and (g)(1)(iii).

[FR Doc. 2016–23851 Filed 10–5–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0570; FRL–9951–67–Region 9]

Approval of California Air Plan Revisions, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) portion of the California State Implementation Plan (SIP). This revision concerns emissions of volatile organic compounds (VOCs), oxides of nitrogen (NO_X), and particulate matter (PM) from wood burning devices. We are approving a local rule that regulates these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule will be effective on November 7, 2016.

ADDRESSES: The EPA has established docket number EPA–R09–OAR–2015–0570 for this action. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps, multi-volume reports), and some may not be available in either location (*e.g.,* confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Rynda Kay, EPA Region IX, (415) 947–4118, *kay.rynda@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. Proposed Action

On September 30, 2015 in 80 FR 58637, the EPA proposed to approve the following rule into the California SIP.

Local agency	Rule No.	Rule title	Amended	Submitted
SJVUAPCD	4901	Wood Burning Fireplaces and Wood Burning Heaters	09/18/14	11/06/14

We proposed to approve this rule because we determined that it complied with the relevant CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, which ended on October 30, 2015, we received comments from Adenike Adeyeye, Earthjustice.[1] Summaries of the comments are provided below, along with our responses to those comments.

Comment #1: Earthjustice commented that, ''[t]he previous iteration of Rule 4901, amended in 2008, banned the use of [all] wood burning devices when the forecasted $PM_{2.5}$ concentration exceeded 30 [micrograms per cubic meter (μg/m³)]'', while the submitted rule allows use of registered devices[2] until forecasted $PM_{2.5}$ concentrations reach 65 μg/m³. Earthjustice argued that this revision, which allows registered devices to burn and emit PM equal to or less than 2.5 microns in diameter ($PM_{2.5}$) while the San Joaquin Valley Air Basin is violating the 2006 24-hour $PM_{2.5}$ standard, constitutes a relaxation of restrictions on burning for registered wood burning devices that violates CAA section 110(l). Earthjustice noted that SJVUAPCD justified this relaxation by predicting drastic emission reductions from replacement of existing wood burning devices, but asserted that SJVUAPCD's claim that the relaxation is irrelevant because the associated emissions are low is incorrect.

Response #1: We disagree with the commenter's claim that the rule revisions are a relaxation that violates CAA section 110(l). As an initial matter, section 110(l) does not prohibit all relaxations of individual SIP-approved rule provisions. Rather, section 110(l) prohibits the EPA from approving a SIP revision that ''would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in [CAA section 171]), or any other applicable requirement of [the CAA].'' The EPA's conclusion that Rule 4901 will not interfere with attainment is not based on low emissions associated with the revision of the SIP to allow registered devices to be used when forecasted concentrations are between 30 and 65 μg/m³, as the commenter asserts. The commenter focuses only on this provision of Rule 4901 and ignores the associated requirement that unregistered devices can no longer be used when forecasted concentrations are above 20 μg/m³. Contrary to the commenter's suggestion, the EPA is not required under section 110(l) to evaluate each individual revision to Rule 4901 separately from all other revisions to Rule 4901. Accordingly, the EPA's analysis of Rule 4901 considers both provisions in conjunction.

As discussed in the EPA's Technical Support Document supporting our proposed approval of Rule 4901 (''Rule 4901 TSD''),[3] SJVUAPCD estimates that reducing the $PM_{2.5}$ forecast level at which unregistered devices are banned from 30 to 20 μg/m³ decreases average wood burning season emissions by 3.33 tons per day (tpd) $PM_{2.5}$, while allowing registered devices to burn when forecasted concentrations are between 30–65 μg/m³ increases emissions by 0.065 tpd $PM_{2.5}$. Combining these changes yields an overall estimated emission reduction of 3.27 tpd $PM_{2.5}$ when compared to the SIP-approved rule.[4] Therefore, projected increases in

[1] Letter and email from Adenike Adeyeye, Earthjustice, dated and received October 30, 2015.

[2] Submitted Rule 4901, Paragraph 5.7.1 sets eligibility requirements for District registration of wood burning heaters that may be used during a Level One Episodic Wood Burning Curtailment. The heaters must be either exempt from EPA certification requirements or EPA-certified as specified under the New Source Performance Standard (NSPS) for New Residential Wood Heaters (40 CFR part 60, subpart AAA) in effect at the time of purchase or installation.

[3] *See* Technical Support Document for the EPA's Proposed Rulemaking for the California State Implementation Plan, San Joaquin Valley Unified Air Pollution Control District Rule 4901, Wood Burning Fireplaces and Wood Burning Heaters, August 2015, (''Rule 4901 TSD'') page 8.

[4] As noted in the Rule 4901 TSD, the SIP-approved version of Rule 4901 contains a contingency provision which would have come into effect if the EPA had found that the SJV had failed to attain the 1997 $PM_{2.5}$ National Ambient Air Quality Standards (NAAQS or ''standards'') by the applicable deadline. That provision would have

Continued

emissions from registered devices are more than offset by the emission reductions achieved by the enhanced curtailment criteria for unregistered stoves. Contrary to the commenter's assertion, this evaluation does not rely on expected additional change-outs to cleaner burning devices, which would lead to additional emission reductions beyond 3.27 tpd $PM_{2.5}$. Thus, the revisions to Rule 4901 are expected to result in significant emission reductions overall compared to the current SIP-approved version of the rule, which will help to expedite attainment of the $PM_{2.5}$ NAAQS in the San Joaquin Valley (SJV). Accordingly, we find that the revisions to Rule 4901 are consistent with the development of an overall plan for attaining the NAAQS in the SJV.

With regard to other applicable requirements of the CAA, for the reasons explained in our proposal, TSD and in response to comments below, we also find that Rule 4901 implements reasonably available control measures (RACM) and best available control measures (BACM) for $PM_{2.5}$ emissions from wood burning devices in the SJV. Therefore, we conclude that the revisions to Rule 4901 will not interfere with any applicable requirement concerning attainment and reasonable further progress or any other applicable requirement of the CAA.

Comment #2: Earthjustice commented that the Bay Area Air Quality Management District (BAAQMD), South Coast Air Quality Management District (SCAQMD), and Sacramento Metropolitan Air Quality Management District (SMAQMD) include more stringent curtailment requirements as they apply to registered devices. In particular, Earthjustice noted that SCAQMD and BAAQMD ban the use of all wood burning devices when the forecasted $PM_{2.5}$ concentration exceeds 30 μg/m³ and 35 μg/m³, respectively. SMAQMD limits burning using a tiered system, banning the use of registered devices when the forecasted $PM_{2.5}$ concentration exceeds 35 μg/m³. As a result, Earthjustice argued that ''[t]he changes to rule 4901 do not meet the requirements for reasonably available control measures (RACM) or BACM for registered wood burning devices.''

Response #2: The commenter appears to assume that we must evaluate RACM and BACM for registered (clean burning) devices separately from RACM and BACM for unregistered devices. We do not agree with this premise. Nothing in the CAA or EPA's implementing regulations requires us to consider the stringency of requirements for registered devices separately from the stringency of requirements for unregistered devices. Furthermore, the purpose of the two-tiered curtailment system is to encourage replacement of unregistered devices with registered devices, so it is reasonable to consider the requirements applicable to registered and unregistered devices together.[5] As explained above, SJVUAPCD estimates that the emissions from registered clean burning devices when concentrations are above 30 μg/m³ will be overwhelmingly compensated for by decreased emissions from unregistered devices when concentrations are between 20–30 μg/m³, making the Rule 4901 curtailment program at least as stringent as or more stringent than these and other analogous curtailment programs.[6] The commenter has not provided information that contradicts the District's assessment in this regard.

Comment #3: Earthjustice asserted that the controls on the installation of wood burning devices in new developments are less stringent than those used by SCAQMD and BAAQMD. In particular, the commenter noted that SCAQMD Rule 445 prohibits the installation of any wood burning device in new development, except where there is no existing infrastructure for natural gas within 150 feet of the property line or those 3,000 feet above sea level.[7] In addition, the commenter stated that ''BAAQMD recently became the first air district in the nation to ban the installation of wood burning devices in any new development.''

Response #3: Rule 4901, Paragraph 5.3 limits the number of wood burning devices that can be installed in new residential developments. In residential developments with a density greater than two dwellings per acre, no wood burning fireplaces are allowed and a maximum of two certified wood burning heaters per acre are allowed. In developments with a density less than or equal to two dwellings per acre, one wood burning fireplace or certified wood burning heater is allowed per dwelling. As discussed in Rule 4901 TSD at page 12, ''SJVUAPCD states that Rule 4901 is more stringent than SCAQMD Rule 445 as it does not exempt any homes at any elevation.[8] Given the lack of any exemptions in Rule 4901, it is reasonable to conclude that Rule 4901 is at least as stringent as SCAQMD Rule 445.'' The commenters have not provided new information to contradict this conclusion.

The ban on wood burning devices in new construction in BAAQMD Regulation 6–3 was enacted on October 21, 2015, more than a year after SJVUAPCD had amended Rule 4901 on September 18, 2014, and does not become effective until November 1, 2016.[9] Given that no other State or district had enacted a complete ban at the time that SJVUAPCD was revising Rule 4901 and conducting its BACM analysis and no such ban has yet become effective in any State or district, we do not believe it is reasonable to disapprove Rule 4901 for failing to include such a ban. However, we recommend that SJVUAPCD evaluate the feasibility of such a ban in the SJV and revise Rule 4901 to include such a ban, if it is found to be feasible.

Comment #4: Earthjustice commented that Rule 4901's incentive of fewer no-burn days for registered devices is inappropriate and unnecessarily adds air pollution. Earthjustice argued that SJVUAPCD's well-funded financial incentives program is sufficient to motivate a switch to registered wood burning devices and allowing these devices to burn additional days is an unnecessary additional incentive. Further, Earthjustice suggested, if the District offers an additional ''incentive of fewer no burn days, the limit for registered devices should be 30 μg/m³, not 65 μg/m³.''

Response #4: The survey conducted for SJVUAPCD found that 24 percent (%) of residents with non-EPA certified wood burning heaters and wood burning fireplaces would transition to cleaner burning devices if provided a discount of up to 50% toward the cost of a new wood burning device and 29% of residents stated they would transition to cleaner devices if allowed to burn

reduced the mandatory curtailment $PM_{2.5}$ forecast threshold from 30 to 20 μg/m³ for all wood burning devices. However, we have not made a finding that the SJV failed to attain the 1997 $PM_{2.5}$ NAAQS by the applicable deadline, so the contingency provision has not been triggered. Moreover, we have withdrawn our approval of and disapproved the State's 2013 Contingency Measure Submittal, which relied, among other things on the contingency provision in Rule 4901. 81 FR 29498 (May 12, 2016). Accordingly, we believe the appropriate point of comparison for purposes of 110(l) is the SIP-approved rule without the contingency measure (*i.e.,* a mandatory curtailment $PM_{2.5}$ forecast threshold of 30 μg/m³ for all wood burning devices).

[5] For example, on page 45 of Final Staff Report for Amendments to the District's Residential Wood Burning Program, SJVUAPCD, dated September 18, 2014, SJVUAPCD explains that 29% of survey respondents indicated that they would replace their current wood burning fireplace or wood burning heater with a cleaner device if allowed to burn more often.

[6] *See* Rule 4901 TSD, page 11.

[7] SCAQMD, Rule 445: Wood Burning Devices, Section f(2) (amended 5/3/13).

[8] *See* Rule 4901 Staff Report, p. 30.

[9] BAAQMD, Regulation 6: Particulate Matter and Visible Emissions, Rule 3: Wood Burning Devices, Section 6-3-306 (amended 10/21/15).

more often.[10] It seems reasonable to conclude that using both strategies in combination should encourage at least some additional change-outs over just providing incentive funding. In reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet minimum criteria set by the CAA and any applicable EPA regulations and are reasonable. We conclude that allowing clean burning devices to burn when the $PM_{2.5}$ concentration is forecasted to be between 20–65 μg/m³ is reasonable and, as described in Response #1 and #2 above, complies with relevant CAA requirements.

Comment #5: Earthjustice argued that the District should be required to incorporate the EPA's recommendations into Rule 4901. In particular, Earthjustice asserted that the District should: (1) Not subsidize the transition to wood burning heaters, which are generally used more frequently than gas fireplaces; (2) require retrofit of existing wood burning fireplaces during major renovations; and (3) require homes where wood burning devices are the sole source of heat to meet current EPA certification requirements. Earthjustice noted that requirements similar to (2) and (3) were recently added to the BAAQMD rule.

Response #5: While we agree that SJVUAPCD should consider eliminating subsidies for transition from fireplaces to wood burning heaters, details regarding the implementation of SJVUAPCD's monetary incentive program have not been submitted into the SIP and are outside of the scope of this rulemaking. Regarding retrofits of wood burning fireplaces during major renovations, at the time of Rule 4901 adoption and proposal, Laguna Beach, California was the only area we were aware of that required fireplace retrofits upon major home renovation. While we recommended SJVUAPCD examine the feasibility of including this provision, its existence in one small southern California city is not a sufficient basis for determining that it is feasible in the much larger and more diverse SJV. As noted by the commenter, on October 21, 2015, BAAQMD adopted a requirement that a gas-fueled, electric, or EPA-certified device be installed upon remodel of a fireplace or chimney where total costs exceed $15,000 and a local building permit is required. Given that no other State or district had adopted a similar provision at the time that Rule 4901 was revised, we do not believe it is reasonable to disapprove Rule 4901 for failing to include such a provision. However, we continue to recommend that SJVUAPCD consider the feasibility of implementing such a provision in the SJV, particularly in light of the newly-enacted BAAQMD provision. Similarly, we do not believe it is reasonable to disapprove Rule 4901 for failing to require sole-source households to meet EPA certification requirements, as no other State or district had adopted a similar provision at the time that Rule 4901 was amended.

In the Rule 4901 TSD, Attachment 1,[11] we compared Rule 4901 to analogous district rules, and found SJVUAPCD implements a collection of measures as stringent as or more stringent than these rules. We agree that SJVUAPCD should consider our recommendations for future rule revisions, but they do not affect our conclusion that Rule 4901, as amended, strengthens the SIP, decreases $PM_{2.5}$ emissions, and currently implements BACM/Best Available Control Technology (BACT) for wood burning devices. Additionally, the rule fulfills the relevant CAA section 110 and Title I Part D requirements. Therefore, we conclude that our recommendations for rule revisions do not provide a basis for rule disapproval.

III. EPA Action

No comments were submitted that change our assessment of the rule as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving this rule into the California SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the SJVUAPCD rule described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available electronically through *www.regulations.gov* and in hard copy at U.S. Environmental Protection Agency Region IX (AIR–4), 75 Hawthorne Street, San Francisco, CA, 94105–3901.

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

[10] *See* Staff Report, Appendix B, p. B–13.

[11] *See* Rule 4901 TSD, Attachment 1. Major Components of Various Residential Wood Burning Rules.xlsx.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 5, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 15, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(364)(i)(A)(*4*) and (c)(457)(i)(H) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(364) * * *

(i) * * *

(A) * * *

(*4*) Previously approved on October 11, 2009 in paragraph (c)(364)(i)(A)(*2*) of this section and now deleted with replacement in paragraph (c)(457)(i)(H)(*1*), Rule 4901, ''Wood Burning Fireplaces and Wood Burning Heaters,'' amended on October 16, 2008.

* * * * *

(457) * * *

(i) * * *

(H) San Joaquin Valley Unified Air Pollution Control District.

(*1*) Rule 4901, ''Wood Burning Fireplaces and Wood Burning Heaters,'' amended on September 18, 2014.

* * * * *

[FR Doc. 2016–24081 Filed 10–5–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0432; FRL–9953–66–Region 9]

Denial of Request for Extension of Attainment Date for 1997 $PM_{2.5}$ NAAQS; California; San Joaquin Valley Serious Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is denying a request submitted by California for extension of the attainment date for the 1997 24-hour and annual fine particulate matter ($PM_{2.5}$) national ambient air quality standards in the San Joaquin Valley Serious $PM_{2.5}$ nonattainment area.

DATES: This rule is effective on November 7, 2016.

ADDRESSES: The EPA has established docket number EPA–R09–OAR–2015–0432 for this action. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps, multi-volume reports), and some may not be available in either location (*e.g.,* confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Rory Mays, Air Planning Office (AIR–2), EPA Region 9, (415) 972–3227, *mays.rory@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. Background
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I. Background

On February 9, 2016, the EPA proposed to approve, conditionally approve, and disapprove state implementation plan (SIP) revisions submitted by California (the ''State'' or California Air Resources Board (CARB)) to address Clean Air Act (CAA or ''Act'') requirements for the 1997 24-hour and annual $PM_{2.5}$ national ambient air quality standards (NAAQS) in the San Joaquin Valley (SJV) Serious $PM_{2.5}$ nonattainment area.[1] The SIP revisions on which we proposed action are the ''2015 Plan for the 1997 $PM_{2.5}$ Standard,'' which the State submitted on June 25, 2015, and the ''2018 Transportation Conformity Budgets for the San Joaquin Valley $PM_{2.5}$ SIP, Plan Supplement,'' submitted on August 13, 2015. We refer to these SIP submissions collectively as the ''2015 $PM_{2.5}$ Plan'' or ''the Plan.'' The 2015 $PM_{2.5}$ Plan is a $PM_{2.5}$ Serious area attainment plan for the SJV and includes a request to extend the applicable attainment date for the 24-hour and annual $PM_{2.5}$ standards by three and five years, respectively, on the basis that attainment by December 31, 2015 is impracticable, in accordance with CAA section 188(e).

The EPA proposed to approve the following elements of the Plan as satisfying applicable CAA requirements: (1) The 2012 base year emissions inventories; (2) the best available control measures (BACM)/best available control technology demonstration; (3) the attainment demonstration; (4) the reasonable further progress demonstration; (5) the State's application for an extension of the Serious area attainment date to December 31, 2018 for the 1997 24-hour $PM_{2.5}$ NAAQS and to December 31, 2020 for the 1997 annual $PM_{2.5}$ NAAQS; (6) the San Joaquin Valley Unified Air Pollution Control District (the ''District''

[1] 81 FR 6936 (February 9, 2016).

or SJVUAPCD) commitment to amend and implement revisions to SJVUAPCD Rule 4692 (''Commercial Charbroiling'') for under-fired charbroilers on a specific schedule; and (7) the motor vehicle emissions budgets for 2014, 2017, 2018, and 2020. Additionally, the EPA proposed to approve the Plan's inter-pollutant trading mechanism for use in transportation conformity analyses, with the condition that trades are limited to substituting excess reductions in emissions of nitrogen oxides (NO_X) for direct $PM_{2.5}$ emission reductions.

The EPA proposed to conditionally approve the Plan's quantitative milestones based on a commitment by the State to adopt specific enforceable measures by a date certain but not later than one year after the date of the Plan approval, consistent with CAA section 110(k)(4). Finally, the EPA proposed to disapprove the Plan's contingency measures for failure to satisfy the requirements of CAA section 172(c)(9).

Section 188(e) of the CAA provides the Administrator with discretionary authority to grant a state's request for an extension of a Serious area attainment date where certain conditions are met. Before the EPA may extend the attainment date for a Serious area under section 188(e), the State must: (1) Apply for an extension of the attainment date beyond the statutory attainment date; (2) demonstrate that attainment by the statutory attainment date is impracticable; (3) have complied with all requirements and commitments pertaining to the area in the implementation plan; (4) demonstrate to the satisfaction of the Administrator that the plan for the area includes the ''most stringent measures'' that are included in the implementation plan of any state or are achieved in practice in any state, and can feasibly be implemented in the area; and (5) submit a demonstration of attainment by the most expeditious alternative date practicable.[2] The EPA's determination of whether such a plan provides for attainment by the most expeditious date practicable depends on whether the plan provides for implementation of BACM no later than the statutory implementation deadline, the most stringent measures (MSM) as expeditiously as practicable, and any other technologically and economically feasible measures that will result in attainment as expeditiously as practicable.

Given the strategy in the nonattainment provisions of the Act to offset longer attainment time frames with more stringent control requirements, the EPA interprets the MSM provision to assure that additional controls that can feasibly be implemented in the area beyond the set of measures adopted as BACM are implemented. Two ways to do this are (1) to require that more sources and source categories be subject to MSM analysis than to BACM analysis and controlled as necessary—*i.e.,* by expanding the applicability provisions in the MSM control requirements to cover more sources, and (2) to require reanalysis of any measures adopted in other areas that were rejected during the BACM analysis because they could not be implemented by the BACM implementation deadline to see if they are now feasible for the area given the longer attainment timeframe.[3]

The EPA provided a 30-day period for public comment on the proposed rule and received comment letters from Mr. Paul Cort, on behalf of Earthjustice, and from Mr. Shawn Dolan. The comments from Earthjustice primarily argued that the control measure analysis in the Plan for several sources categories, including ammonia emission sources, glass melting furnaces, and internal combustion engines used in agricultural operations, fail to satisfy CAA requirements. The comments from Mr. Shawn Dolan argued that EPA Method 9 should be phased out in favor of other methods for evaluating visible emissions such as the Digital Camera Opacity Technique (DCOT).

II. Final Action on Section 188(e) Extension Request

Based on our reevaluation of the 2015 $PM_{2.5}$ Plan and related control measures and consideration of the comments we received, the EPA is denying CARB's request for extension of the December 31, 2015 Serious area attainment date for the 1997 $PM_{2.5}$ NAAQS in the SJV. As explained in our proposed rule, one of the minimum criteria for extension of an attainment date under CAA section 188(e) is that the state demonstrate to the satisfaction of the Administrator that the plan for the area includes the most stringent measures that are included in the implementation plan of any state or are achieved in practice in any state, and can feasibly be implemented in the area. For a number of source categories, CARB and the SJVUAPCD have demonstrated that the SIP includes the most stringent measures required or achieved in practice in other areas. For the following reasons, however, we find that CARB and the SJVUAPCD have not demonstrated to the EPA's satisfaction that the plan for the SJV area includes all MSM that can feasibly be implemented in the area.

First, the 2015 $PM_{2.5}$ Plan does not adequately demonstrate that it includes MSM for sources of ammonia emissions in the SJV.[4] As explained in our proposed rule, three source categories collectively emitted 95% of all ammonia emissions in the 2012 annual average base year inventory for the SJV area: Confined animal facilities (CAFs), composting operations, and fertilizer application.[5] The 2015 $PM_{2.5}$ Plan states that three SIP-approved rules designed to limit volatile organic compound (VOC) emissions also control ammonia emissions from two of these source categories (*i.e.,* CAFs and composting operations) but does not substantiate these conclusions. For example, according to the 2015 $PM_{2.5}$ Plan, many of the VOC control measures in SJVUAPCD Rule 4570 (''Confined Animal Facilities''), as amended October 21, 2010, have an ammonia ''co-benefit,'' and these measures have reduced ammonia emissions in the SJV by over 100 tons per day (tpd).[6] The 2015 $PM_{2.5}$ Plan does not, however, specifically identify any enforceable requirement in SJVUAPCD Rule 4570 that reduces ammonia emissions from CAF operations, nor does it substantiate its calculation of ammonia emission reductions attributed to SJVUAPCD Rule 4570 other than by reference to an outdated analysis from 2006.[7] Moreover, a number of provisions in SJVUAPCD Rule 4570 allow CAF owners/operators to implement ''alternative mitigation

[2] *Id.* at 6940.

[3] *Id.* at 6941.

[4] As we explained in our proposed rule, the EPA does not agree at this time with the State's and District's conclusion in the Plan that ammonia emissions do not contribute significantly to $PM_{2.5}$ levels exceeding the $PM_{2.5}$ standards in the SJV. 81 FR 6936, 6948 (February 9, 2016). Accordingly, consistent with the regulatory presumption under subpart 4 of part D, title I of the Act, ammonia emission sources are subject to control evaluation for purposes of implementing the 1997 $PM_{2.5}$ NAAQS in the SJV.

[5] 81 FR 6936, 6978 (February 9, 2016); *see also* 2015 $PM_{2.5}$ Plan, Appendix C, p. C–239.

[6] 2015 $PM_{2.5}$ Plan, Appendix C, pp. C–239 to C–240.

[7] 2015 $PM_{2.5}$ Plan, Appendix C, pp. C–239 to C–275 and SJVUAPCD, ''Final Draft Staff Report, Proposed Re-Adoption of Rule 4570 (Confined Animal Facilities),'' June 18, 2009, at Appendix F, ''Ammonia Reductions Analysis for Proposed Rule 4570 (Confined Animal Facilities),'' June 15, 2006 (discussing various assumptions underlying the District's calculation of ammonia emission factors without identifying relevant emissions inventories). We note that CARB has provided the EPA with significantly lower estimates of ammonia emission reductions achieved by SJVUAPCD Rule 4570 based on more recent calculations of reductions from a 2012 baseline emissions inventory. Email dated September 3, 2015, from Gabe Ruiz (CARB) to Larry Biland and Andrew Steckel (EPA), regarding ''SJV Livestock Ammonia Emissions with and without Rule 4570.''

measures'' [8] *in lieu of* the mitigation measures listed in the rule, without any requirement to ensure that such alternative mitigation measures achieve any particular level of ammonia emission reductions.[9] We find these analyses in the 2015 $PM_{2.5}$ Plan insufficient to demonstrate that the plan includes MSM for ammonia emissions from CAFs in the SJV. Because emissions from CAFs account for more than half of all ammonia emissions in the SJV,[10] a more robust analysis of potential ammonia emission reduction measures for this source category is necessary to satisfy the MSM requirement.

Similarly, the 2015 $PM_{2.5}$ Plan states that SJVUAPCD Rule 4565 (''Biosolids, Animal Manure, and Poultry Litter Operations''), as adopted March 15, 2007, and SJVUAPCD Rule 4566 (''Organic Material Composting Operations''), as adopted August 18, 2011, limit ammonia emissions from composting operations but does not specifically identify any enforceable requirement in either of these rules that reduces ammonia emissions, nor does it identify a basis for the District's statement that ''the [ammonia] control efficiencies are assumed to be the same as the VOC control efficiencies . . . since the same control measures will reduce both VOC and [ammonia] from these operations.'' [11] By contrast, South Coast Air Quality Management District (SCAQMD) Rule 1133.2 (''Emission Reductions from Co-Composting Operations''), as adopted January 10, 2003, and SCAQMD Rule 1133.3 (''Emission Reductions from Greenwaste Composting Operations''), as adopted July 8, 2011, both contain specific requirements to reduce ammonia emissions and, in some cases, to achieve an overall ammonia emission reduction of at least 80% by weight from specified baseline levels.[12]

With respect to fertilizer application, the 2015 $PM_{2.5}$ Plan discusses ongoing research on improved methods of fertilizer application to maximize nitrogen use efficiency and minimize air and water quality impacts and states that ''the weight of evidence suggests that managing nutrient applications to fields . . . has significantly reduced losses of nitrogen compounds to the environment, including leaching of nitrogen compounds to groundwater and air emissions such as ammonia and nitrous oxide.'' [13] The 2015 $PM_{2.5}$ Plan does not, however, provide any specific analysis of potential control measures to reduce ammonia emissions from fertilizer application or identify any enforceable SIP requirement that reduces ammonia emissions from this source category.

In sum, the 2015 $PM_{2.5}$ Plan fails to identify any specific, enforceable requirement to reduce ammonia emissions in the SIP for the area and does not demonstrate that the State or District adequately considered potential control measures to expand or strengthen the reasonably available control measure (RACM) strategy for ammonia emission sources.[14] We therefore find the District's analyses in the 2015 $PM_{2.5}$ Plan insufficient to demonstrate that the plan includes MSM for ammonia emission sources in the SJV.

Second, the 2015 $PM_{2.5}$ Plan does not adequately demonstrate that it includes MSM for NO_X emissions from internal combustion engines used in agricultural operations in the SJV. SJVUAPCD Rule 4702, as amended November 14, 2013, regulates NO_X emissions from two types of agricultural internal combustion (IC) engines rated at 25 brake horsepower (bhp) or greater: Spark-ignited (SI) engines and compression-ignited (CI) engines.[15] For SI engines used in agricultural operations, the rule establishes NO_X emission limits of 90 parts per million by volume (ppmv) for rich-burn engines and 150 ppmv for lean-burn engines.[16] For CI engines used in agricultural operations, Rule 4702 requires compliance by specified dates with EPA Tier 3 or Tier 4 NO_X emission standards for non-road CI engines in 40 CFR part 89 or part 1039, as applicable, or an 80 ppmv NO_X emission limit, depending on engine type.[17]

SCAQMD Rule 1110.2, by contrast, establishes an 11 ppmv NO_X emission limit for all stationary SI and CI engines rated over 50 bhp, effective July 1, 2011, with limited exceptions for agricultural engines that meet certain conditions.[18] According to the SCAQMD, three natural gas-fired SI engines used in agricultural operations are currently subject to the 11 ppmv NO_X emission limit in Rule 1110.2 and use nonselective catalytic reduction (NSCR, also called ''three-way catalysts'') control technology to comply with this emission limit.[19] The Feather River Air Quality Management District (FRAQMD) Rule 3.22, as amended October 6, 2014, establishes NO_X emission limits of 25 parts per million (ppm) and 65 ppm for rich-burn and lean-burn agricultural engines in southern FRAQMD, respectively, except for agricultural engines that emit less than 50% of the major source thresholds for regulated air pollutants and/or hazardous air pollutants.[20] The NO_X emission limits for agricultural engines in SCAQMD Rule 1110.2 and FRAQMD Rule 3.22 are significantly more stringent than the 90 ppmv and 150 ppmv limits applicable to agricultural

[8] ''Alternative Mitigation Measure'' is defined in SJVUAPCD Rule 4570 as ''a mitigation measure that is determined by the APCO, ARB, and EPA to achieve reductions that are equal to or exceed the reductions that would be achieved by other mitigation measures listed in this rule that owners/operators could choose to comply with rule requirements.'' SJVUAPCD Rule 4570 (amended October 21, 2010), section 3.4. Because SJVUAPCD Rule 4570 explicitly applies only to VOC emissions, the requirement for equivalent ''reductions'' in section 3.4 applies only to VOC emission reductions and does not apply to ammonia emission reductions.

[9] *See, e.g.,* SJVUAPCD Rule 4570 (amended October 21, 2010) at section 5.6, Table 4.1.F.

[10] 2015 $PM_{2.5}$ Plan, Appendix B, pp. B–17 and B–19.

[11] 2015 $PM_{2.5}$ Plan, Appendix C, pp. C–271 to C–278.

[12] SCAQMD Rule 1133.2 (adopted January 10, 2003), section (d) and SCAQMD Rule 1133.3 (adopted July 8, 2011), section (d).

[13] 2015 $PM_{2.5}$ Plan, Appendix C, pp. C–268 to C–271.

[14] The SJVUAPCD's Moderate area plan for the 2006 $PM_{2.5}$ NAAQS, adopted in 2012, relies upon the same SIP-approved VOC control measures to satisfy RACM requirements for these NAAQS. *See* EPA, Final Rule, ''Approval and Promulgation of Air Quality State Implementation Plans; California; San Joaquin Valley; Moderate Area Plan for the 2006 $PM_{2.5}$ NAAQS,'' August 16, 2016 (pre-publication notice).

[15] SJVUAPCD Rule 4702 (amended November 14, 2013), sections 2.0 and 5.2.

[16] *Id.* at section 5.2.3 and Table 3.

[17] *Id.* at section 5.2.4 and Table 4 and section 3.37 (defining Tier 1, Tier 2, Tier 3, and Tier 4 engines).

[18] SCAQMD Rule 1110.2 (amended February 1, 2008), section (d)(1) (referencing Tables I and II). Rule 1110.2 provides an exemption from the 11 ppmv emission limit for agricultural engines that meet EPA Tier 4 emission standards and either of two additional conditions: (1) The engine operator submits documentation to the SCAQMD, by the deadline for a permit application, that the applicable electric utility has rejected an application for an electrical line extension to the location of the engines, or (2) the SCAQMD determines that the operator does not qualify for funding under California Health and Safety Code Section 44229 to replace, retrofit or repower the engine. SCAQMD Rule 1110.2 at section (h)(9).

[19] Email dated May 3, 2016, from Kevin Orellana (SCAQMD) to Nicole Law (EPA), regarding ''Question on Engines under Rule 1110.2.''

[20] FRAQMD Rule 3.22 (amended October 6, 2014), section D.1, Table 2 (South FRAQMD Emission Limits) and section B.1.e (Exemptions). As of June 2016, staff at the FRAQMD were unaware of any stationary SI engines currently operating at agricultural facilities in the Feather River area that have demonstrated compliance with the 25 ppm or 65 ppm NO_X emission limits in FRAQMD Rule 3.22. *See* email dated June 2, 2016, from Alamjit Mangat (FRAQMD) to Nicole Law (EPA), regarding ''Engines in FRAQMD'' (stating that all 423 agricultural engines currently operating in the Feather River area qualify for an exemption from the NO_X emission limits in FRAQMD Rule 3.22). Nonetheless, because these NO_X emission limits are approved into the California SIP as part of an earlier version of FRAQMD Rule 3.22 (*see* 77 FR 12493, March 1, 2012), they are required as MSM if they can feasibly be implemented in the SJV.

engines in SJVUAPCD Rule 4702. Moreover, SJVUAPCD Rule 4702 itself establishes NO_X emission limits for IC engines used in other (non-agricultural) operations that range from 11 to 50 ppmv for rich-burn engines and 11 to 75 ppmv for lean-burn engines, depending on type of fuel and use.[21]

In Appendix C of the 2015 $PM_{2.5}$ Plan, the SJVUAPCD estimated the following costs of replacing agricultural SI engines: $76,209 per ton to replace a lean-burn engine to meet an 11 ppmv NO_X limit; $42,146 per ton to replace a lean-burn engine to meet a 65 ppmv NO_X limit; $59,754 per ton to replace a rich-burn engine to meet an 11 ppmv NO_X limit; and $69,521 per ton to replace a rich-burn engine to meet a 25 ppmv NO_X limit.[22] The District subsequently submitted additional information indicating that the cost of replacing a lean-burn engine to meet 65 ppmv or 25 ppmv NO_X limits would be the same as the replacement cost to meet an 11 ppmv NO_X limit ($76,209 per ton), as selective catalytic reduction (SCR) would be necessary for a lean-burn engine to meet any of these limits, and indicating that the cost of replacing a rich-burn engine to meet a 65 ppmv NO_X limit would also be the same as the replacement cost to meet 25 ppmv or 11 ppmv NO_X limits ($59,754 or $69,521 per ton), as three-way catalysts (NSCR) would be necessary for a rich-burn engine to meet any of these limits.[23] The SJVUAPCD did not, however, identify the bases for any of these cost estimates or submit related technical documentation. At the EPA's request, the SJVUAPCD provided additional information about the technological and economic feasibility of IC engine retrofits to meet lower NO_X limits but similarly did not identify the bases for its cost estimates or provide any related technical documentation.[24] Moreover, according to the SCAQMD, the cost-effectiveness of replacing an agricultural SI engine ranges from $5,650 to $29,000 per ton of NO_X reduced and, for most engine categories, is below $20,000 per ton.[25]

Given the absence of a technical basis for the SJVUAPCD's cost estimates for engine replacements or retrofits, the contrary information presented by the SCAQMD regarding costs for the same type of engines, and the significantly lower NO_X emission levels achieved in practice in the South Coast area, as well as the lower NO_X limits for similar engines required in SIP-approved rules for both the Feather River area and the SJV, we find the District's analyses in the 2015 $PM_{2.5}$ Plan insufficient to demonstrate that the plan includes MSM for NO_X emissions from IC engines used in agricultural operations.

Third, the 2015 $PM_{2.5}$ Plan does not adequately demonstrate that it includes MSM for NO_X emissions from container glass melting furnaces in the SJV. SJVUAPCD Rule 4354, as amended May 19, 2011, establishes a NO_X emission limit of 1.5 pounds of NO_X per ton (lbs NO_X/ton) of glass pulled, over a 30-day rolling average.[26] Under the SCAQMD's Regional Clean Air Incentives Market (RECLAIM) Program, the SCAQMD determined in 2000 that a NO_X limit of 1.2 lbs NO_X/ton of glass pulled represented Best Available Retrofit Control Technology (BARCT)[27] for glass melting furnaces, and in 2015 the SCAQMD determined that a lower NO_X limit of 0.24 lbs NO_X/ton of glass pulled represents BARCT for this source category based on use of SCR or the ''Ultra Cat ceramic filter system,'' which the SCAQMD found is guaranteed to achieve an 80% NO_X reduction and has been installed or is under construction at 12 glass manufacturing locations worldwide.[28] The Owens-Brockway Glass Container facility, which manufactures clear and colored beer bottles, is the only glass melting facility currently operating in the South Coast area.[29] At the EPA's request, the SCAQMD provided continuous emission monitoring system (CEMS) data from February 2015 for the Owens-Brockway facility. The CEMS data shows that the facility operated at approximately 90% production capacity and consistently emitted below 0.72 lbs NO_X/ton of glass pulled during that month, using oxyfuel firing to control NO_X emissions.[30]

According to the SJVUAPCD, NO_X emissions from glass melting facilities operating oxyfuel or SCR systems can vary widely depending on multiple factors, including the stability of the glass pull rate and the condition and age of the furnace refractory and insulation.[31] The SJVUAPCD states that glass melting facilities in the SJV manufacture a large variety of sizes and shapes of still and sparkling wine glass bottles and often must respond to fluctuating demands in the wine industry, which require operators to use their furnaces in a manner that results in a less stable pull rate compared to facilities located in the South Coast, which mainly produce beer bottles. Additionally, according to the SJVUAPCD, as furnaces age the refractory is not as effective at retaining heat in the furnace and the burner fire rate must be increased over time to maintain the same overall furnace and glass temperature, which increases NO_X emissions on a lb/ton basis. The District states that all of these factors result in varied NO_X emission rates depending on production conditions, furnace age, and furnace design.[32] The District did not, however, submit or reference any technical documentation to support its conclusions about the feasibility of lower NO_X emission limits for glass melting furnaces in the SJV. Given the absence of a technical basis for the SJVUAPCD's conclusions about the feasibility of more stringent controls for glass melting furnaces, and the available information from the SCAQMD about significantly lower NO_X emission levels that have been achieved in practice both in the South Coast and elsewhere, we find the District's analyses in the 2015 $PM_{2.5}$ Plan insufficient to demonstrate that the plan includes MSM for NO_X emissions from container glass melting furnaces.

Finally, the 2015 $PM_{2.5}$ Plan does not adequately demonstrate that the State and District reevaluated, for potential adoption, control measures rejected

[21] SJVUAPCD Rule 4702 (amended November 14, 2013), section 5.2.1. Table 1 and section 5.2.2. Table 2.

[22] 2015 $PM_{2.5}$ Plan, Appendix C, pp. C–132 to C–139.

[23] Email dated April 27, 2016, from Sheraz Gill (SJVUAPCD) to Andrew Steckel (EPA), regarding ''Additional SJV info.''

[24] Email dated June 25, 2015, from Sheraz Gill (SJVUAPCD) to Andrew Steckel (EPA), regarding ''Requested Information.''

[25] Email dated May 3, 2016, from Kevin Orellana (SCAQMD) to Nicole Law (EPA), regarding ''Question on Engines under Rule 1110.2.''

[26] SJVUAPCD Rule 4354 (amended May 19, 2011), section 5.1.

[27] BARCT is defined as ''an emission limitation that is based on the maximum degree of reduction achievable taking into account environmental, energy, and economic impacts by each class or category of source.'' California Health & Safety Code Section 40406.

[28] The RECLAIM program requires that container glass melting facilities achieve NO_X reductions consistent with the 2015 BARCT determination (0.24 lbs NO_X/ton of glass pulled) by 2022. SCAQMD Rule 2002 (as amended December 4, 2015), subparagraph (f)(1)(L) and Table 6 (''RECLAIM NO_X 2022 Ending Emission Factors''); *see also* SCAQMD, Draft Final Staff Report, ''Proposed Amendments to Regulation XX, Regional Clean Air Incentives Market (RECLAIM), NO_X RECLAIM,'' December 4, 2015, at pp. 170–171.

[29] Email dated May 13, 2016, from Kevin Orellana (SCAQMD) to Idalia Perez (EPA) regarding ''question regarding SCAQMD boilers and container glass facility;'' *see also* email dated April 28, 2016, from Kevin Orellana (SCAQMD) to Idalia Perez (EPA) regarding ''question regarding SCAQMD boilers and container glass facility.''

[30] Email dated April 13, 2016, from Kevin Orellana (SCAQMD) to Idalia Perez (EPA) regarding ''question regarding SCAQMD boilers and container glass facility.''

[31] Email dated April 27, 2016, from Sheraz Gill (SJVUAPCD) to Andrew Steckel (EPA) regarding ''Additional SJV info.''

[32] *Id.*

during the State's and District's development of the previous attainment plan for the 1997 $PM_{2.5}$ NAAQS in the SJV area (the ''2008 $PM_{2.5}$ Plan'') [33] in accordance with the EPA's longstanding interpretation of the MSM requirement. As explained in our proposed rule, given the strategy in the nonattainment provisions of the Act to offset longer attainment time frames with more stringent control requirements, the EPA interprets the MSM provision to assure that additional controls that can feasibly be implemented in the area beyond the set of measures adopted as BACM are implemented. Two ways to do this are (1) to require that more sources and source categories be subject to MSM analysis than to BACM analysis and controlled as necessary—*i.e.,* by expanding the applicability provisions in the MSM control requirements to cover more sources, and (2) to require reanalysis of any measures adopted in other areas that were rejected during the BACM analysis because they could not be implemented by the BACM implementation deadline to see if they are now feasible for the area given the longer attainment timeframe.[34] In this case, because CARB submitted both the BACM demonstration required under CAA section 189(b)(1)(B) and the MSM demonstration required under CAA section 188(e) simultaneously, we compared the BACM and MSM analyses in the 2015 $PM_{2.5}$ Plan with the previous RACM analysis carried out by the District to support the 2008 $PM_{2.5}$ Plan.

The 2015 $PM_{2.5}$ Plan identifies four District control measures not included in the RACM control strategy that the EPA approved as part of the 2008 $PM_{2.5}$ Plan.[35] Collectively, these four District measures are projected to achieve a total of 0.0357 tpd of NO_X emission reductions and 3.3 tpd of direct $PM_{2.5}$ emission reductions by 2018 and to achieve a total of 0.4011 tpd of NO_X emission reductions and 2.0 tpd of direct $PM_{2.5}$ emission reductions by 2020.[36] The MSM evaluation in the 2015 $PM_{2.5}$ Plan provides little discussion of actions to either expand the applicability provisions in the RACM control measures to cover more sources, or to reanalyze measures that were rejected during the previous RACM analysis to see if they are now feasible for the area given the longer attainment timeframe (*i.e.,* the extended attainment dates requested by the State). While the Plan provides the District's conclusions that its existing SIP control measures satisfy BACM and MSM requirements and that no additional control measures are feasible, it provides limited technical support for these conclusions.[37] We note that many of the SJVUAPCD rules that the 2015 $PM_{2.5}$ Plan relies on to address the MSM requirement have not been revised in many years [38] and that the State and District should conduct a more comprehensive evaluation of potential measures to strengthen these regulations, subject to notice-and-comment rulemaking, to ensure expeditious attainment of the 1997 $PM_{2.5}$ NAAQS in the SJV.

In light of the deficiencies in the MSM analyses, we find that the State and District have not demonstrated to the EPA's satisfaction that the 2015 $PM_{2.5}$ Plan includes the most stringent measures that are included in the implementation plan of any state or are achieved in practice in any state, and can feasibly be implemented in the area, in accordance with the requirements of CAA section 188(e). For these reasons, the EPA is denying CARB's request for extension of the December 31, 2015 Serious area attainment date under CAA section 188(e) for the 1997 $PM_{2.5}$ NAAQS in the SJV.

We note that the EPA had proposed to grant the State's requested extension of the Serious area attainment date in the SJV for the reasons explained in our February 9, 2016 proposed action on the 2015 $PM_{2.5}$ Plan. Public comments on our proposal, however, presented information indicating that our proposal to grant the requested extension would not be consistent with the requirements of the Act. Our proposal to grant the State's request for extension of the Serious area attainment date raised the question as to whether the 2015 $PM_{2.5}$ Plan satisfied the minimum criteria in CAA section 188(e) for such extensions. Implicit in any such proposal to grant an extension requested by a state is the possibility that the EPA may decide to deny the extension, after considering public comments. Because our February 9, 2016 proposed rule provided adequate notice of both the possibility that the EPA would grant the State's request for extension of the attainment date for the SJV and the possibility that the EPA would deny this request, we are not providing additional opportunity for comment before this final action takes effect.

The EPA is taking final action only to deny the State's requested extension of the attainment date for the 1997 $PM_{2.5}$ NAAQS in the SJV and is not finalizing its proposed actions on other elements of the 2015 $PM_{2.5}$ Plan at 81 FR 6936 (February 9, 2016) at this time. The EPA will take final action on the remaining portions of the submitted 2015 $PM_{2.5}$ Plan, as appropriate, in a subsequent rulemaking.

III. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law.

[33] 76 FR 69896 (November 9, 2011) (final rule approving most elements of 2008 $PM_{2.5}$ Plan).

[34] 81 FR 6936, 6941 (February 9, 2016); *see also* EPA, Final Rule, ''Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements,'' 81 FR 58010, 58096–58097 (August 24, 2016).

[35] 81 FR at 6973–6975 (February 9, 2016). The four District control measures are: (1) Rule 4308 (''Boilers, Steam Generators, and Process Heaters 0.075 to <2 MMBtu/hr''), as amended November 14, 2013; (2) an enforceable commitment to amend Rule 4692 (''Commercial Charbroiling'') in 2016 to add requirements for under-fired charbroilers; (3) Rule 4901 (''Wood Burning Fireplaces and Wood Burning Heaters''), as amended September 18, 2014; and (4) Rule 4905 (''Natural Gas-Fired, Fan-Type Residential Central Furnaces''), as amended January 22, 2015.

[36] *Id.* at 6975, Table 9.

[37] *See generally* 2015 $PM_{2.5}$ Plan, Appendix C (BACM and MSM for Stationary and Area Sources).

[38] *See, e.g.,* 2015 $PM_{2.5}$ Plan, Appendix C at pp. C–106 to C–114 (discussing SJVUAPCD Rule 4550, as adopted August 19, 2004); pp. C–194 to C–197 (discussing SJVUAPCD Rule 8061, as amended August 19, 2004); and pp. C–275 to C–278 (discussing SJVUAPCD Rule 4565, as adopted March 15, 2007).

Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 5, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ammonia, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: September 23, 2016.

Alexis Strauss,

Acting Regional Administrator, EPA Region 9.

[FR Doc. 2016–24082 Filed 10–5–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0121; FRL–9951–90]

Dichlormid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dichlormid in or on all commodities for which there is a tolerance for metolachlor and S-metolachlor. Drexel Chemical Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 6, 2016. Objections and requests for hearings must be received on or before December 5, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0121, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance

regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0121 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before December 5, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0121, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of April 25, 2016 (81 FR 24044) (FRL–9944–86), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP IN–10858) by Drexel Chemical Company, P.O. Box 13327, Memphis, TN 38113–03227. Although the notice announced the petition requested that 40 CFR 180.469 be amended by establishing tolerances for residues of the inert ingredient (safener) dichlormid, in or on all commodities for which there is a tolerance for metolachlor and S-metolachlor at 0.05 parts per million (ppm), the notice of filing submitted simply listed numerous commodities that were intended to correspond to the commodities for which metolachlor and s-metolachlor tolerances were established. That document referenced a summary of the petition prepared by Drexel Chemical Company, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

To ensure consistency between the notice of filing and the petition filed and to avoid any confusion, EPA requested that Drexel revise and resubmit their notice of filing to clarify that the request is to establish tolerances for residues of the inert ingredient (safener) dichlormid, in or on all commodities for which there is a tolerance for metolachlor and S-metolachlor at 0.05 ppm. Upon receiving that revised petition, EPA issued a notice of filing of that petition pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3) in the **Federal Register** of July 20, 2016 (81 FR 47150) (FRL–9948–45). The petition requested that 40 CFR 180.469 be amended by establishing tolerances for residues of the inert ingredient (safener) dichlormid, in or on all commodities for which there is a tolerance for metolachlor and S-metolachlor at 0.05 ppm. That revised petition prepared by Drexel Chemical Company, the registrant, is available in the docket, *http://www.regulations.gov.* There was one comment received in response to this notice of filing; however, the comment was not related to this chemical or petition and is therefore, not relevant to this action.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for dichlormid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with dichlormid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The database for dichlormid has been previously reviewed by the Agency, most recently March 23, 2011 when the permanent tolerance for dichlormid was issued (76 FR 16308) (FRL–8866–2). No new data was reviewed as part of this petition for tolerance.

Specific information on the studies received and the nature of the adverse effects caused by dichlormid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

In acute toxicity studies, dichlormid exhibits low to moderate toxicity, depending on the route of exposure. The oral lethal dose $(LD)_{50}$ for dichlormid in rats is 2,816 milligram/kilogram (mg/kg) in males and 2,146 mg/kg for females (Category III). The dermal LD_{50} of dichlormid in rats is greater than 2,000 mg/kg (Category III). The acute inhalation lethal concentration $(LC)_{50}$ in rats is greater than 5.5 mg/(L) (Category IV). Dichlormid is mildly irritating to the skin of rabbits (Category IV) and severely irritating to the eyes of rabbits

(Category II). Dichlormid is a mild dermal sensitizer.

The liver is the target organ in subchronic and chronic toxicity studies in rats and dogs. There are two 90-day rat toxicity studies are available. One older study (1972), was determined to be an unacceptable study. In the other study, toxicity was manifested as minor decreased in body weight gains and food efficiency in females and on increased liver weight and a slightly increased (not statistically significant) incidence of liver lipidosis in males. Similarly two 90-day toxicity studies in dogs are available. In the newer study, via capsules, decreased body weight gains, hematological and clinical chemistry alternations, liver toxicity and voluntary muscle pathological changes were observed. In a 1-year toxicity study in the dogs, voluntary muscle fiber degeneration and slight to moderate vacuolation of the adrenal cortex was observed at 20 mg/kg/day. There was also increased in alkaline phosphatase activity in both sexes and decreased in aspartate aminotransferase activity in females. Liver weights (absolute and relative to body) were increased in both sexes.

In a developmental toxicity study in rats, decreased mean absolute body weights, body weight gains, and food consumption was observed in maternal animals. Developmental toxicity in rats was manifested as marginal increased in skeletal anomalies in the presence of maternal toxicity. In the developmental toxicity study in rabbits, increased incidence of alopecia and decreased mean maternal body weight gains and food consumption was observed in maternal animals. The fetal effects in rabbits, exhibited in the presence of maternal toxicity, were manifested as increases in post-implantation loss accompanied by an increase number of resorptions/doe (both early and late resorptions), decreased number of live/fetuses/litter, and slightly decreased mean fetal body weights. In a 2-generation reproduction study in rats, no treatment related effects on reproductive parameters were observed. Minimal increased liver weight, minimal decreased weight gain and minimal decreased in food consumption was observed in parental animals. Increased liver weights were observed in the offspring.

No increased incidences of treatment related tumors were observed in mice and rats. In the carcinogenicity study in mice, kidney changes and changes in reproductive organs were observed, while rats exhibited decreased body weights and liver toxicity. Mutagenic potential for dichlormid was evaluated in an adequate battery of *in vivo* and *in vitro* assays. A negative response was observed in these assays except in one *in vitro* assay (mouse lymphoma assay). However, the *in vivo* mouse micronucleus assay was negative.

In an acute neurotoxicity study in rats, decreased body weight gains with lower food consumption was observed in both sexes. Functional observational battery (FOB) measurements at the time of peak effect (4 hrs post dose) showed decreased activity, hunching, increased touch response, lachrimation, piloerection, reduced splay reflex, and signs of salivation. These effects were deemed slight with a greater incidence in females. No treatment-related changes in bodyweight, food consumption, FOB, motor activity, brain weight, or neuropathology were identified in the 90-day neurotoxicity study in rats; however, the high dose of 750 ppm (equal to 55.4 mg/kg/day) was not considered as adequate for testing. No evidence of immunotoxicity was observed in a dietary immunotoxicity study in rats. There were no treatment related effects on spleen and thymus weights at any of the doses of dichlormid tested.

Approximately 90% of the orally administered dose was absorbed in rats. Urinary excretion was the major route of elimination of orally administered dichlormid, consistently accounting for 60–78% of the administered dose over 48–168 hours following a single oral dose. Fecal excretion accounted for ~8–20% of a single oral dose. Approximately 70–77% of urinary excretion (representing 52–54% of the administered dose) occurred within 24 hours. No gender-related difference in rate or amount of urinary excretion was observed. No significant accumulation in the body was observed. Dichlormid was metabolized via two pathways:

1. Initial dechlorination followed by formation of various chlorinated, water-soluble metabolites, and;

2. Formation of various chlorinated metabolites.

In a subchronic inhalation toxicity study in rats via whole body exposure for 6 hours a day, 5 days/week for 14 weeks, decreased body weights and increased liver weights were observed at the highest dose tested. The increased liver weights was considered as an adaptive response. Chromorhinorrhea, a respiratory system clinical observation based on the discharge of colored secretion from the nostrils, was exhibited consistently in the two top dose exposure groups. Microscopic pathology identified in the two top dose exposure groups, dose-dependent respiratory tract tissue alterations involving the olfactory epithelium for both genders.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for dichlormid used for human health risk assessment are shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DICHLORMID USE IN HUMAN RISK ASSESSMENT [1]

Exposure scenario	Dose and factors	FQPA SF and endpoint for risk assessment	Study and toxicological effects
Acute Dietary, *all populations* including infants and children.	NOAEL = 10 mg/kg UF = 100 Acute RfD = 0.10 mg/kg/day	FQPA SF = 1 aPAD = acute RfD/ FQPA SF = 0.10 mg/kg/day	Developmental Toxicity Study—Rat Maternal LOAEL = 40 mg/kg/day based on decreased body weight gain and food consumption (most significant on days 7–10 of dosing).
Chronic Dietary, *all populations*	NOAEL = 5 mg/kg/day. UF = 100 Chronic RfD = 0.05 mg/kg/day.	FQPA SF = 1 cPAD = chr RfD/ FQPA SF = 0.05 mg/kg/day.	1-year Study—Dog LOAEL = 20 mg/kg/day (male, female), based on increased liver weights, increased in alkaline phosphatase activity, minimal muscle fiber degeneration in, slight to moderate vacuolation of the inner cortex of the adrenal gland, and increased kidney weights (females).
Dermal Absorption	100% default; neither a dermal absorption study nor a dermal toxicity study (for extrapolation) is available in the database.		
Short-term Dermal	Oral NOAEL = 10.0 mg/kg/day.	MOE = 100	Developmental toxicity Study—Rats Maternal LOAEL = 40 mg/kg/day based on decreased body weight gain and food consumption (most significant on days 7–10 of dosing). This dose/endpoint/study was used for deriving the aRfD. Dermal toxicity study is not available. 100% dermal absorption factor should be used for this risk assessment.
Intermediate- and Long-Term (Dermal).	Oral NOAEL = 5 mg/kg/day.	MOE = 100	1-year study—Dog LOAEL = 20 mg/kg/day (male, female), based on increased liver weights, increased in alkaline phosphatase activity, minimal muscle fiber degeneration in, slight to moderate vacuolation of the inner cortex of the adrenal gland, and increased kidney weights (females).
Inhalation (All Durations)	2 μg/L	MOE = 100	14-week inhalation study LOAEL = 20 μg/L based on clinical signs, increased liver and kidney weights, gross pathology and non-neoplastic histopathology. The route of exposure in this study is appropriate for this risk assessment.
Cancer			No evidence of carcinogenicity in rats and mice.

[1] UF = uncertainty factor; FQPA SF = FQPA Safety Factor; NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level; PAD = population adjusted dose (a = acute, c = chronic); RfD = reference dose; LOC = level of concern; MOE = margin of exposure.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dichlormid, EPA considered exposure under the petitioned-for tolerances as well as all existing dichlormid tolerances in 40 CFR 180.469. The assessment was conducted using the proposed tolerance of 0.05 ppm for those commodities for which there is a current tolerance for metolachlor and S-metolachlor as well as for all commodities to account for the potential dietary exposure that could result from dichlormid should additional tolerances be established for metolachlor and S-metolachlor. EPA assessed dietary exposures from dichlormid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for dichlormid. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance level residues (*i.e.,* 0.05 ppm) and 100% crop treated.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 CSFII. As to residue levels in food, EPA used tolerance level residues (*i.e.,* 0.05 ppm) and 100% crop treated.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that dichlormid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for dichlormid. Tolerance level residues (*i.e.,* 0.05 ppm) and 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* For the current screening level dietary risk assessment, to support the request for expanded tolerances for dichlormid, a conservative drinking water concentration value of 100 parts per billions (ppb), based on screening level modeling, was used to account for the contribution of the additional commodities to drinking water for the chronic dietary risk assessments for the parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Dichlormid is not contained in any pesticide formulation registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether

to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found dichlormid to share a common mechanism of toxicity with any other substances, and dichlormid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dichlormid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of infants and children from *in utero* exposure to dichlormid based on developmental toxicity study in rats. In this study the developmental toxicity was manifested as marginal increased in skeletal anomalies (developmental toxicity NOAEL 40 mg/kg/day) at a one dose higher than the NOAEL for maternal toxicity (NOAEL 10 mg/kg/day). There is qualitative evidence of increased susceptibility demonstrated following *in utero* exposure in the prenatal developmental toxicity study in rabbits, since fetal effects observed (resorptions, decreased live fetuses per litter, and decreased fetal body weight) are considered to be more severe than those observed in maternal animals (increased alopecia, decreased body weight gain and food consumption). In this study the NOAEL for maternal and developmental toxicity is 30 mg/kg/day. There is no evidence increased susceptibility of infants and children from pre-and post-natal exposure to dichlormid in the two generation reproduction study. In this study, increased liver, weights, decreased body weight gain and decreased food consumption was observed in parental animals and increased liver weights in the offspring.

There is no/low concern for increased qualitative susceptibility seen in the developmental toxicity study in rabbits because there is well characterized NOAEL for the developmental toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for dichlormid is complete. All part 158 data requirements are fulfilled. The dichlormid toxicity database included subchronic studies in rats and dogs, mutagenicity battery, carcinogenicity studies in mice and rats, developmental toxicity study in rats and rabbits, 2-generation reproduction study, acute and subchronic neurotoxicity study, immunotoxicity study, metabolism and repeat dose inhalation toxicity study.

ii. There is no indication that dichlormid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity based on acute and subchronic neurotoxicity study.

iii. There is no evidence that dichlormid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. There was some evidence of increased qualitative susceptibility seen in the developmental toxicity study in rabbits, however, there is no residual uncertainty or concern because there is well characterized NOAEL for the developmental toxicity and regulatory end points are below the NOAEL for the developmental effects thus providing additional margin of safety.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to dichlromid in drinking water. These assessments will not underestimate the exposure and risks posed by dichlromid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to dichlormid will occupy 26.2% of the aPAD for all infants (<1 year old), the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to dichlormid from food and water will utilize 15.3% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for dichlormid.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, dichlormid is not contained in any pesticide product registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for dichlormid.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, dichlormid is not contained in any pesticide product registered for any use patterns that would result in intermediate-term

residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for dichlormid.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity, dichlormid is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to dichlormid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with nitrogen selective thermionic detection) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for dichlormid.

V. Conclusion

Therefore, tolerances are established for residues of dichlormid, in or on all commodities for which there is a tolerance for metolachlor and S-metolachlor at 0.05 ppm as listed in 40 CFR 180.368.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 27, 2016.

Michael Goodis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.469, redesignate the existing paragraph (a) as (a)(1), and add paragraph (a)(2) to read as follows:

§ 180.469 Dichlormid; Tolerances for residues.

(a) *General.* (1) * * *

(2) Tolerances are established for residues of dichlormid, including its metabolites and degradates, at 0.05 parts per million (ppm) when used as an inert ingredient (herbicide safener) in pesticide formulations containing metolachlor or S-metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor or S-metolachlor. Compliance with the tolerances is to be determined by measuring only

dichlormid (2,2-dichloro-*N,N*-di-2-propenylacetamide).

* * * * *

[FR Doc. 2016–24214 Filed 10–5–16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258

[EPA–R09–RCRA–2015–0445; FRL–9953–45–Region 9]

Final Determination To Approve Site-Specific Flexibility for Closure and Monitoring of the Picacho Landfill

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency, Region IX, is making a final determination to approve two Site-Specific Flexibility Requests (SSFRs) from Imperial County (County or Imperial County) to close and monitor the Picacho Solid Waste Landfill (Picacho Landfill or Landfill). The Picacho Landfill is a commercial municipal solid waste landfill (MSWLF) operated by Imperial County from 1977 to the present on the Quechan Indian Tribe of the Fort Yuma Indian Reservation in California.

EPA is promulgating a site-specific rule proposed on April 7, 2016, that approves an alternative final cover and a modification to the prescribed list of groundwater detection-monitoring parameters for ongoing monitoring for the Picacho Landfill.

DATES: This final rule is effective on October 6, 2016.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R09–RCRA–2015–0445. All documents in the docket are listed in the *http://www.regulations.gov* index. Publicly available docket materials are available electronically in *http://www.regulations.gov* and in hard copy at the EPA Library, located at the Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, California. The EPA Library is open from 9:00 a.m. to 4:00 p.m., Monday through Thursday, excluding legal holidays, and is located in a secured building. To review docket materials at the EPA Library, it is recommended that the public make an appointment by calling (415) 947–4406 during normal business hours. Copying arrangements will be made through the EPA Library and billed directly to the recipient. Copying costs may be waived depending on the total number of pages copied.

FOR FURTHER INFORMATION CONTACT: Steve Wall, Land Division, Mail Code LND 2–3 U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105–3901; telephone number: (415) 972–3381; fax number: (415) 947–3564; email address: *wall.steve@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What did EPA propose?

After completing a review of Imperial County's Picacho Landfill Final Closure/Post-Closure Maintenance Plan and the associated SSFRs, EPA proposed this rulemaking in the **Federal Register**. The proposed determination was published at 81 FR 20274, April 7, 2016. EPA proposed to approve an alternative final cover that varies from the final closure requirements of 40 CFR 258.60(a) but meets the criteria at 40 CFR 258.60(b), and alternative groundwater detection monitoring parameters for post-closure monitoring in accordance with 40 CFR 258.54(a).

II. Legal Authority for This Action

Under sections 1008, 2002, 4004, and 4010 of the Resource Conservation and Recovery Act of 1976 (RCRA) as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6901 *et seq.,* Congress required EPA to establish revised minimum federal criteria for MSWLFs, including landfill location restrictions, operating standards, design standards, and requirements for ground water monitoring, corrective action, closure and post-closure care, and financial assurance. Under RCRA section 4005, states are to develop permit programs for facilities that may receive household hazardous waste or waste from conditionally exempt small quantity generators of hazardous waste, and EPA is to determine whether the state's program is adequate to ensure that such facilities will comply with the revised federal criteria.

The MSWLF criteria are set forth in the Code of Federal Regulations at 40 CFR part 258. These regulations are prescriptive, self-implementing and apply directly to owners and operators of MSWLFs. Many of these criteria include a flexible performance standard as an alternative to the prescriptive, self-implementing regulation. The flexible standard is not self-implementing, and requires approval by the Director of an EPA-approved state MSWLF permitting program. However, EPA's approval of a state program generally does not extend to Indian Country because states generally do not have authority over Indian Country. For this reason, owners and operators of MSWLF units located in Indian Country cannot take advantage of the flexibilities available to those facilities that are within the jurisdiction of an EPA-approved state program. However, the EPA has the authority under sections 2002, 4004, and 4010 of RCRA to promulgate site-specific rules to enable such owners and operators to use the flexible standards. See *Yankton Sioux Tribe* v. *EPA,* 950 F. Supp. 1471 (D.S.D. 1996); *Backcountry Against Dumps* v. *EPA,* 100 F.3d 147 (D.C. Cir. 1996). EPA refers to such rules as ''Site-Specific Flexibility Determinations.'' EPA has developed guidance for owners and operators on preparing a request for such a site-specific rule, entitled ''Site-Specific Flexibility Requests for Municipal Solid Waste Landfills in Indian Country, Draft Guidance,'' EPA530–R–97–016 (August 1997) (Draft Guidance).

III. Background

The Picacho Landfill is located on Quechan tribal lands on the Fort Yuma Indian Reservation approximately four miles north-northeast of the community of Winterhaven, in Imperial County, California. The Picacho Landfill is a commercial MSWLF operated by Imperial County from 1977 to the present. The landfill site is approximately 12.5 acres.

In January 2006, the Tribe requested that EPA provide comments on the County's closure plan. Between 2006 and 2011, EPA worked with the Tribe, the Bureau of Indian Affairs (BIA) and the County to develop the closure plan. During this time, EPA also reviewed the SSFRs to determine whether they met technical and regulatory requirements. On October 27, 2010, Imperial County submitted its Picacho Final Closure/Post-Closure Maintenance Plan. EPA provided a final round of comments on February 10, 2011, which Imperial County incorporated as an addendum. On April 30, 2012, the Tribe approved the Picacho Landfill Final Closure/Post-Closure Maintenance Plan as amended, and, pursuant to EPA's Draft Guidance, the Tribe forwarded to EPA two SSFRs that had been submitted by Imperial County to close and monitor the Picacho Landfill. The requests sought EPA approval to use an alternative final cover meeting the performance requirements of 40 CFR 258.60(a), and to modify the prescribed list of groundwater detection-monitoring parameters provided in 40 CFR 258.54(a)(1) and (2) for ongoing monitoring.

IV. Basis for Final Determination

EPA is basing its final determination to approve the site-specific flexibility requests on the Tribe's approval, dated April 30, 2012, EPA's independent review of the Picacho Landfill Final Closure/Post-Closure Maintenance Plan as amended, and the associated SSFRs.

A. Alternative Final Cover SSFR: Alternative Final Cover System

The regulations require the installation of a final cover system specified in 40 CFR 258.60(a), which consists of an infiltration layer with a minimum of 18 inches of compacted clay with a permeability of 1×10^{-5} cm/sec, covered by an erosion layer with a minimum six inches of topsoil. Imperial County sought approval for an alternative final cover designed to satisfy the performance criteria specified in 40 CFR 258.60(b); Imperial County proposed to replace this with an alternative cover consisting of two and a half feet of native soil to control infiltration covered by six inches of a soil gravel mixture to control erosion.

EPA is basing its final determination on a number of factors, including: (1) Research showing that prescriptive, self-implementing requirements for final covers, comprised of low permeability compacted clay, do not perform well in the arid west. The clay dries out and cracks, which allows increased infiltration along the cracks; (2) Research showing that in arid environments thick soil covers comprised of native soil can perform as well or better than the prescriptive cover; and (3) Imperial County's analysis demonstrates, based on site-specific climatic conditions and soil properties, that the proposed alternative soil final cover will achieve equivalent reduction in infiltration as the prescriptive cover design and that the proposed erosion layer provides equivalent protection from wind and water erosion. This analysis is provided in Appendix D and Appendix D–1 of the Picacho Landfill Final Closure/Post-Closure Maintenance Plan dated October 27, 2010 and amended by EPA's comments dated February 20, 2011.

B. Groundwater Monitoring SSFR: Alternative Detection Monitoring Parameters

The regulations require post-closure monitoring of 15 heavy metals, listed in 40 CFR part 258, Appendix I. Imperial County proposed to replace these, with the exception of arsenic, with the alternative inorganic indicator parameters chloride, nitrate as nitrogen, sulfate, and total dissolved solids.

EPA's final determination is based on the fact that the County has performed over 15 years of semi-annual groundwater monitoring at the site, and during that time arsenic was the only heavy metal detected at a value that slightly exceeded the federal maximum contaminant level (MCL), a standard used for drinking water.

V. Summary of Public Comments Received and Response to Comments

EPA received one anonymous public comment during the public comment period stating support for EPA's Tentative Determination to Approve Site-Specific Flexibility for Closure and Monitoring of the Picacho Landfill, as proposed in the **Federal Register** on April 7, 2016.

VI. Additional Findings

In order to comply with the National Historic Preservation Act, 54 U.S.C. 100101 *et seq.,* Imperial County Department of Public Works will coordinate with the Tribe to arrange for a qualified Native American monitor to be present during any work. If buried or previously unidentified resources are located during project activities, all work within the vicinity of the find will cease, and the provisions of 36 CFR 800.13(b) will be implemented. If, during the course of the Landfill closure activities, previously undocumented archaeological material or human remains are encountered, all work shall cease in the immediate area and a qualified archaeologist shall be retained to evaluate the significance of the find and recommend further management actions.

Though no known threatened or endangered species or their habitat exist on the site, in order to ensure compliance with the Endangered Species Act, 16 U.S.C. 1536 *et seq.,* a preconstruction survey will be conducted prior to cover installation to ensure no threatened or endangered species are present. In particular, the survey will look for the presence of desert tortoises, which may occur in Imperial County. Should desert tortoises or other threatened or endangered species be encountered in the survey, or at any time during the closure of the Picacho Landfill, the County shall contact the U.S. Fish and Wildlife Service to develop avoidance measures to ensure that impacts to the species are minimized. Following closure and vegetation restoration activities, the project site may become suitable for threatened and endangered species. This would be a beneficial effect.

Under Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), this rule is not of general applicability and therefore is not a regulatory action subject to review by the Office of Management and Budget (OMB).

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) because it applies to a particular facility only.

Because this rule is of particular applicability relating to a particular facility, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202, 204, and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Because this rule will affect only a particular facility, it will not significantly or uniquely affect small governments, as specified in section 203 of UMRA.

Because this rule will affect only a particular facility, this proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, ''Federalism,'' (64 FR 43255, August 10, 1999). Thus, Executive Order 13132 does not apply to this rule.

This rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks posed by this action present a risk to children. The basis for this belief is EPA's analysis of the potential risks posed by Imperial County's alternative final cover and alternative groundwater detection-monitoring parameters proposals and the standards set forth in this rulemaking.

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

As required by section three of Executive Order 12988, ''Civil Justice Reform,'' (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments,'' (65 FR 67249, November 9, 2000), calls for EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' *See* also ''EPA Policy for the Administration of Environmental Programs on Indian Reservations,'' (November 8, 1984) and ''EPA Policy on Consultation and Coordination with Indian Tribes,'' (May 4, 2011). EPA consulted with the Quechan Tribe throughout Imperial County's development of its closure and monitoring plans for the Picacho Landfill.

List of Subjects in 40 CFR Part 258

Environmental protection, Final cover, Monitoring, Municipal landfills, Post-closure care groundwater, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: September 22, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

For the reasons stated in the preamble, 40 CFR part 258 is amended as follows:

PART 258—CRITERIA FOR MUNICIPAL SOLID WASTE LANDFILLS

■ 1. The authority citation for part 258 continues to read as follows:

Authority: 33 U.S.C. 1345(d) and (e); 42 U.S.C. 6902(a), 6907, 6912(a), 6944, 6945(c) and 6949a(c), 6981(a).

Subpart F—Closure and Post-Closure Care

■ 2. Section 258.62 is amended by removing ''[Reserved]'' at the end of the section and adding paragraph (b) to read as follows:

§ 258.62 Approval of site-specific flexibility requests in Indian country.

* * * * *

(b) *Picacho Municipal Solid Waste Landfill—alternative list of detection monitoring parameters and alternative final cover.* This paragraph (b) applies to the Picacho Landfill, a Municipal Solid Waste Landfill operated by Imperial County on the Quechan Indian Tribe of the Fort Yuma Indian Reservation in California.

(1) In accordance with § 258.54(a), the owner and operator may modify the list of heavy metal detection monitoring parameters specified in appendix I of this part, as required during Post-Closure Care by § 258.61(a)(3), by replacing monitoring of the inorganic constituents, with the exception of arsenic, with the inorganic indicator parameters chloride, nitrate as nitrogen, sulfate, and total dissolved solids.

(2) In accordance with § 258.60(b), the owner and operator may replace the prescriptive final cover set forth in § 258.60(a), with an alternative final cover as follows:

(i) The owner and operator may install an evapotranspiration cover system as an alternative final cover for the 12.5 acre site.

(ii) The alternative final cover system shall be constructed to achieve an equivalent reduction in infiltration as the infiltration layer specified in § 258.60(a)(1) and (2), and provide an equivalent protection from wind and water erosion as the erosion layer specified in § 258.60(a)(3).

(iii) The final cover system shall consist of a minimum three-foot-thick multi-layer cover system comprised, from bottom to top, of:

(A) A minimum 30-inch thick infiltration layer consisting of:

(*1*) Existing intermediate cover; and

(*2*) Additional cover soil which, prior to placement, shall be wetted to optimal moisture and thoroughly mixed to near uniform condition, and the material shall then be placed in lifts with an uncompacted thickness of six to eight inches, spread evenly and compacted to 90 percent of the maximum dry density, and shall:

(*i*) Exhibit a grain size distribution that excludes particles in excess of three inches in diameter;

(*ii*) Have a minimum fines content (percent by weight passing U.S. No. 200 Sieve) of seven percent for an individual test and eight percent for the average of ten consecutive tests;

(*iii*) Have a grain size distribution with a minimum of five percent smaller than five microns for an individual test and six percent for the average of ten consecutive tests; and

(*iv*) Exhibit a maximum saturated hydraulic conductivity on the order of 1.0E–03 cm/sec.; and

(*3*) A minimum six-inch surface erosion layer comprised of a rock/soil admixture. The surface erosion layer admixture and gradations for 3% slopes and 3:1 slopes are detailed below:

(*i*) 3% slopes: For the 3% slopes the surface admixture shall be composed of pea gravel (⅜-inch to ½-inch diameter) mixed with cover soil at the ratio of 25% rock to soil by volume with a minimum six-inch erosion layer.

(*ii*) For the 3:1 side slopes the surface admixture shall be composed of either: gravel/rock (¾-inch to one-inch diameter) mixed with additional cover soil as described in paragraph (b)(2)(iii)(A)(*2*) of this section at the ratio of 50% rock to soil by volume and result in a minimum six-inch erosion layer, or gravel/rock (¾-inch to two-inch diameter) mixed with additional cover soil as described in paragraph (b)(2)(iii)(A)(*2*) of this section at the ratio of 50% rock to soil by volume and result in a minimum 12-inch erosion layer.

(*iii*) The owner and operator shall place documentation demonstrating compliance with the provisions of this section in the operating record.

(*iv*) All other applicable provisions of this part remain in effect.

(B) [Reserved]

[FR Doc. 2016–23839 Filed 10–5–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 02–376, RM–10617, RM–10690; DA 16–1062]

Radio Broadcasting Services; Sells, Willcox, and Davis-Monthan Air Force Base, Arizona

AGENCY: Federal Communications Commission.

ACTION: Final rule; dismissal of application for review.

SUMMARY: In this document, the Media Bureau (Bureau) dismisses as moot the Application for Review filed jointly by KZLZ, LLC (KZLZ) and Lakeshore Media, LLC, the current and former licensee, respectively, of Station KWCX–FM. While the AFR was pending, KZLZ filed a minor modification application to change the community of license of Station KWCX–FM from Willcox to Tanque Verde, Arizona. Once the requested facility modification to Station KWCX–FM was granted, the assignment at Willcox was deleted, and this in turn rendered moot any Section 307(b) comparison between Davis-Monthan AFB and the deleted Willcox assignment.

DATES: Effective October 6, 2016.

FOR FURTHER INFORMATION CONTACT: Adrienne Denysyk, Media Bureau, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Bureau's *Letter,* DA 16–1062, released September 21, 2016. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554.

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. This document is not subject to the Congressional Review Act. (The Commission, is, therefore, not required to submit a copy of the *Letter* to GAO, pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A) because the Application for Review was dismissed as moot.)

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 2016–24174 Filed 10–5–16; 8:45 am]

BILLING CODE 6712–01–P

SURFACE TRANSPORTATION

49 CFR Parts 1108 and 1115

[Docket No. EP 730]

Revisions to Arbitration Procedures

AGENCY: Surface Transportation Board.

ACTION: Final rules.

SUMMARY: The Surface Transportation Board (Board or STB) adopts changes to its arbitration procedures to conform to the requirements of the Surface Transportation Reauthorization Act of 2015.

DATES: These rules are effective on October 30, 2016.

ADDRESSES: Information or questions regarding these final rules should reference Docket No. EP 730 and be in writing addressed to: Chief, Section of Administration, Office of Proceedings, Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Amy C. Ziehm at 202–245–0391. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: Under Section 13 of the STB Reauthorization Act (codified at 49 U.S.C. 11708), the Board must ''promulgate regulations to establish a voluntary and binding arbitration process to resolve rail rate and practice complaints'' that are subject to the Board's jurisdiction. Section 11708 sets forth specific requirements and procedures for the Board's arbitration process. While the Board's existing arbitration regulations [1] are for the most part consistent with the new statutory provisions, certain changes are needed so that the Board's regulations conform fully to the requirements under section 11708.

On May 12, 2016, the Board issued a Notice of Proposed Rulemaking (NPR), proposing to modify its existing arbitration regulations, set forth at 49 CFR part 1108 and 49 CFR 1115.8, to conform to the provisions set forth by the statute and to make other minor clarifying changes. Specifically, the Board proposed adding rate disputes to the list of matters eligible for arbitration under its arbitration program and barring two matters from the arbitration program (disputes to prescribe for the future any conduct, rules, or results of general, industry-wide applicability and disputes solely between two or more rail carriers). For rate disputes, pursuant to section 11708(c)(1)(C), the proposed rules indicated that arbitration would be available only if the rail carrier has market dominance (as determined under 49 U.S.C. 10707). The Board sought comment on whether parties should be given the option to concede market dominance, thereby forgoing the need for a determination by the Board under 49 U.S.C. 10707.

The Board also proposed that, as an alternative to filing a written complaint, arbitration could be initiated by the parties if they submit a joint notice to the Board indicating their consent to arbitrate. In accordance with section 11708(g), the Board proposed setting the maximum amount of relief that could be awarded under the arbitration program to $25,000,000 in rate disputes and $2,000,000 in practice disputes. The Board also proposed rules to establish a process for creating and maintaining a roster of arbitrators and selecting arbitrators from the roster in accordance with section 11708(f). Pursuant to section 11708(d) and (h), the proposed rules would also modify the requirements for, and applicable standard of review of, arbitration decisions, which are to be ''consistent with sound principles of rail regulation economics.'' The proposed rules would also modify the deadlines governing the arbitration process in accordance with the statutory provisions. Lastly, the proposed rules would correct an inadvertent omission made in Docket No. EP 699 that unintentionally removed the Board's standard of review for labor arbitration cases.

The Board sought comments on the proposed regulations by June 13, 2016, and replies by July 1, 2016. The Board received comments from seven parties: Association of American Railroads (AAR), American Chemistry Council (ACC), National Grain and Feed Association (NGFA), Growth Energy, Rail Customer Coalition (RCC), National Industrial Transportation League (NITL), and Samuel J. Nasca on behalf of SMART/Transportation Division, New York State Legislative Board (SMART/TD–NY). AAR, ACC, and SMART/TD–NY also filed replies. After giving consideration to the comments and suggestions submitted by parties, the Board clarifies and modifies its proposed rules, as discussed below.

Creating and Maintaining the Roster. Under section 11708(f)(1), arbitrators on the roster must be ''persons with rail transportation, economic regulation, professional or business experience, including agriculture, in the private sector.'' The NPR further proposed that arbitrators be required to have training in dispute resolution and/or experience in arbitration or other forms of dispute resolution. Under the proposed rules, the Chairman would have discretion as to whether an individual meets the qualifications to be added to the roster.

NGFA and ACC suggest revising the proposed rules so that all Board members would have input as to which applicants are qualified and should be included in the roster. (NGFA Comments 6, ACC Comment 4.) The Board agrees that all Board Members should have input in establishing the roster of arbitrators. (*See* NGFA Comments 6.) The final rules will provide that the Chairman will solicit input and recommendations from all Members in selecting qualified individuals to be included in the arbitrator roster, which will then be established by a Board no-objection vote.

AAR asserts that the Board should have no discretion to exclude qualified individuals from the roster. (AAR Comment 5.) Rather, AAR suggests that the Board adopt a more transparent process in which individuals meeting set criteria would automatically be added to the roster. Under this process, an applicant would submit a narrative describing his or her qualifications, which would then be posted for a 20-day comment period. (AAR Comment 6.) The Board would add all uncontested applicants to the roster, but if there is an objection, the Board would decide whether the individual should or should not be added and issue a decision explaining its reasoning. (*Id.*) The Board finds this additional process

[1] In *Assessment of Mediation & Arbitration Procedures,* EP 699 (STB served May 13, 2013), the Board adopted modified rules governing the use of mediation and arbitration to resolve matters before the Board. The rules established a new arbitration program under which shippers and carriers may voluntarily agree in advance to arbitrate certain disputes with clearly defined limits of liability.

to be unnecessarily inflexible for creating and maintaining a roster of qualified individuals. Soliciting input from all Board Members concerning the roster, and requiring a final Board no-objection vote as discussed above, should ensure that a comprehensive list of qualified arbitrators with necessary expertise is developed. Additionally, allowing for Board input and discretion is consistent with the statutory requirement that the roster be ''maintained by the Board.'' 49 U.S.C. 11708(f).

AAR suggests that the Board establish additional qualifications for arbitrators, such as ''10 years of experience and a professional reputation for fairness, integrity and good judgment.'' (AAR Comment 5.) The Board finds the additional qualifications suggested by AAR to be unnecessary. The rules adopted here require individuals seeking to be on the roster to have training in dispute resolution and/or experience in arbitration or other forms of dispute resolution. To that end, individuals seeking to be on the roster should include in their notice to the Board details about their relevant training and/or experience (including the number of years of experience). In creating and maintaining the roster, Board Members will thus be able to assess each applicant's qualifications and determine which individuals could ably serve as arbitrators based on the criteria established in these rules. In addition, the parties can make their own assessments regarding an arbitrator's ''fairness, integrity, and good judgment'' during the party-driven selection process we are adopting, discussed below under ''Selection of Arbitrators.''

We are adopting the proposal in the NPR to publish the roster on the Board's Web site to allow the parties to make that assessment of the arbitrators' qualifications. AAR also suggests that each arbitrator's fees and area(s) of expertise be included on the roster. (AAR Comment 6.) The Board agrees that publication of each arbitrator's fees and area(s) of expertise would be helpful to the parties in selecting an arbitrator and has amended the proposed rules accordingly.

Lastly, the NPR proposed that the Chairman, at any time, may add qualified individuals to the roster. The Board clarifies here that the names of eligible arbitrators who have consented to being included on the roster would only be added by a Board no-objection vote.

Selection of Arbitrators. The NPR proposed revising the arbitration selection process to be used when parties cannot mutually agree on a single arbitrator or lead arbitrator of a panel of arbitrators. The Board proposed that it would provide parties a list of not more than 15 arbitrators culled from the Board's roster. The parties would then select a single or lead arbitrator by alternately striking names from the list until only one remains, in accordance with section 11708(f)(3)(A).

AAR proposes a two-step, party-driven approach to selecting a single or lead arbitrator. (AAR Comment 6–8.) First, parties would be given the opportunity to remove individuals from the roster for cause in their particular dispute, such as partiality or lack of independence. Second, each party would submit a list of up to 10 potential arbitrators. If only one arbitrator appears on both lists, he or she would be selected as the single or lead arbitrator. If multiple arbitrators appear on both lists, the parties would alternatively strike names until one remains, beginning with the complainant. If no name appears on both lists, the parties would alternatively strike from the Board's entire roster, as culled by those that are disqualified for cause. In its reply, ACC expressed support of AAR's approach, but stressed that the standard for removing an arbitrator from the roster must be defined narrowly and require clear evidence of bias. (ACC Reply 3.)

The Board agrees that a party-driven approach to selecting an arbitrator is preferable, as parties are in the best position to assess whether an arbitrator is suitable for a particular dispute. However, the first step of AAR's proposal presents the need to define the standard for removing a name from the roster and could potentially require the Board to determine whether a name on the roster was properly removed ''for cause.'' This could turn selection of the arbitrator into a cumbersome and adversarial process, when the purpose of arbitration is supposed to be an expedited alternative to adjudication. Accordingly, the final rules will adopt AAR's two-step approach to selecting a single or lead arbitrator, but modified so that, under the first step, rather than allowing parties to remove arbitrators for cause, each party will be given three peremptory strikes to remove names from the entire roster without offering a reason.[2] Then, as proposed by AAR, from the remaining arbitrators on the roster, each party would submit a list of up to 10 potential arbitrators. If only one arbitrator appears on both lists, he or she would be selected as the single or lead arbitrator. If multiple arbitrators appear on both lists, the parties would alternatively strike names of the jointly listed arbitrators until one remains, beginning with complainant. If no name appears on both lists, the parties would alternatively strike from the Board's entire roster, as amended based on the peremptory strikes.

Arbitration Decisions. Under section 11708(c)(3) and the proposed rules at 49 CFR 1108.4, an arbitrator or panel of arbitrators resolving rate reasonableness disputes shall consider the Board's methodologies for setting maximum lawful rates, giving due consideration to the need for differential pricing to permit a rail carrier to collect adequate revenues (as determined under 49 U.S.C. 10704(a)(2)). As for the actual arbitration decisions, in accordance with section 11708(d), the proposed rule at 49 CFR 1108.9 states, ''[a]ll arbitration decisions must be consistent with sound principles of rail regulation economics.'' Likewise, in accordance with section 11708(h), the proposed rule at 49 CFR 1108.11 states that, ''[t]he Board will review a decision to determine if the decision is consistent with sound principles of rail regulation economics.''

AAR requests that the Board revise the proposed rules so that the language contained in § 1108.4 be added to the proposed rules regarding arbitration decisions at §§ 1108.9 and 1108.11. (AAR Comment 3.) Specifically, AAR would require arbitration decisions resolving rate disputes to ''give due consideration to the need for differential pricing to permit a rail carrier to collect adequate revenues (as determined under section 10704(a)(2)).'' AAR would also include this requirement under the Board's standard of review. ACC argues that AAR's proposed changes are unnecessary, because, under the proposed rules, arbitration decisions ''must be consistent with sound principles of rail regulation economics,'' which include differential pricing. (ACC Reply 1–2.) ACC asserts that adopting AAR's proposal would inappropriately add requirements to arbitration decisions beyond what the statute

[2] The Board will limit peremptory strikes because otherwise parties could strike all names on the list except that party's top choice. If that were to happen, then under our rules, the parties would revert to alternatively striking names from the entire roster, which would defeat the purpose of allowing parties to help cull the roster before the alternative-striking process starts. It is reasonable to allow each party three peremptory strikes. Prior to the modified arbitration regulations adopted in Docket No. EP 699, the Board maintained a roster of arbitrators, which had around 35 individuals. Using that roster as a guide, three peremptory strikes per party would allow the parties to cull about 20% of the roster before the alternative-striking process begins, which is a substantial percentage. Moreover, our rule is similar to 28 U.S.C. 1870, which allows each party in federal civil litigation three peremptory challenges in selecting a jury.

provides and would broaden the Board's standard of review. (*Id.*)

The Board agrees that this additional language would go beyond the statutory requirements for arbitration decisions, and effectively broadens the Board's narrow standard of review. AAR's proposed changes to §§ 1108.9 and 1108.11 will therefore not be adopted.

Under the proposed rule at § 1108.9, an unredacted draft of the arbitration decision would be made available to the parties to the dispute. AAR requests that the final rule account for the fact that an arbitration decision may contain highly confidential information that should be made available only to opposing outside counsel and not be made available to in-house personnel. (AAR Comment 4.) The Board agrees and will adopt AAR's suggested language. The final rule at § 1108.9 will require an unredacted draft to be issued in accordance with any protective order governing the release of confidential and highly confidential information pursuant to § 1108.7(e).

Under the current rule at 49 CFR 1108.11(a), appeals of arbitration decisions are to be filed ''within 20 days of service of a final arbitration decision.'' NGFA requests that the 20-day period begin when the parties receive the arbitration decision, as opposed to when ''a final arbitration decision is reached.'' (NGFA Comment 7.) The current rules are unclear as to whether the 20-day period begins upon service on the parties (30 days after the close of evidentiary period) or on the Board (60 days after the close of evidentiary period). The Board clarifies here that the 20-day period to file an appeal will begin upon service of the arbitration decision upon the Board, and the final rules at §§ 1108.11 and 1115.8 will include language to that effect. This clarification should address NGFA's concern, as parties should receive the arbitration decision well before the decision is served on the Board.

NGFA requests that the Board require arbitration decisions to be made public by posting them on the Board's Web site. (NGFA Comment 7.) Under the current rule at § 1108.9(g), redacted copies of the arbitration decisions are published and maintained on the Board's Web site. Therefore, no changes to the proposed rules are required.

Rate Disputes. Many parties submitted comments on the proposed rules pertaining to the arbitration of rate disputes.

Conceding market dominance. In accordance with section 11708(c)(1)(C), arbitration of rate disputes is only available if the rail carrier has market dominance (as determined under 49 U.S.C. 10707). In the NPR, the Board sought comment on whether parties should be given the option to concede market dominance when agreeing to arbitrate a rate dispute (thereby forgoing the need for a determination from the Board) or, alternatively, whether the Board should limit the availability of the arbitration process in rate disputes to cases where market dominance is conceded. Several parties supported the option for a rail carrier to concede market dominance. (ACC Comment 3, Growth Energy Comment 1, RCC Comment 2, NITL Comment 2.) AAR and NGFA would limit arbitration to situations where market dominance is conceded. (AAR Comment 3, NGFA Comment 3.) Some shippers propose establishing criteria that would trigger a rebuttable presumption of market dominance, such as criteria based on limit price methodology, competitive switching availability, or revenue adequacy. (RCC Comment 2; ACC Comment 4.)

Recognizing that the arbitration process is voluntary and that market dominance determinations may significantly delay the arbitration process, the Board will allow parties to concede market dominance in rate disputes. Parties will also have the option to arbitrate rate disputes where market dominance is not conceded. The Board envisions it would be a rare situation in which the parties disagree on whether there is market dominance but agree to arbitrate a rate dispute. In such a situation, however, there is nothing in the statute that technically prohibits parties from arbitrating. That is, if parties agree to arbitrate, but only upon a finding of market dominance from the Board, they could request a ruling from the Board solely on the issue of market dominance. The Board declines to adopt a rebuttable presumption of market dominance in these rules, as proposed by ACC and RCC, as it would be inconsistent with the complainant's burden to prove market dominance under the statute. 49 U.S.C. 10707; 5 U.S.C. 556(d); *CSX Corp.—Control & Operating Leases/Agreements—Conrail Inc.,* 3 S.T.B. 196, 266 (1998); *Gov't of the Territory of Guam* v. *Sea-Land Serv., Inc.,* WCC 101, slip op. at 5–6 (STB served Feb. 2, 2007).

Use of alternative methodologies. As discussed above, under section 11708(c)(3) and the proposed rule at 49 CFR 1108.4, an arbitrator or panel of arbitrators resolving rate reasonableness disputes shall consider the Board's methodologies for setting maximum lawful rates, giving due consideration to the need for differential pricing to permit a rail carrier to collect adequate revenues (as determined under 49 U.S.C. 10704(a)(2)). Arbitration decisions ''must be consistent with sound principles of rail regulation economics.'' 49 U.S.C. 11708(d). Several shippers assert that arbitrators should have the flexibility to use alternatives to the Board's methodologies (*e.g.,* the Stand-Alone Cost or Three-Benchmark methodologies) or be allowed to modify the application of these methodologies in resolving rate disputes. (NGFA Comment 5, ACC Comment 2, RCC Comment 1–2.) AAR opposes the use of ''untested methodologies'' and ''methodologies rejected by the agency and the courts.'' (AAR Reply 3–4.)

The statutory provisions require arbitrators in rate disputes to ''consider'' Board methodologies, and the final arbitration decision ''must be consistent with sound principles of rail regulation economics.'' section 11708(d)(1). The Board finds that this language is adequate to address the commenters' concerns.

Five-year rate prescription. AAR asks that the Board's rules reflect the requirement set forth in section 11708(g)(3)(B) that rate prescriptions be limited to five years. (AAR Comment 4.) The Board will amend its rule at § 1108.8 accordingly, noting that an arbitrator may grant relief in the form of a rate prescription in rate disputes, but that the rate prescription shall not exceed five years from the date of the arbitration decision.

Definition of ''Rate Disputes.'' NGFA recommends that the Board clarify that ''rate disputes,'' under the proposed § 1108.1(m), involve more than ''a rail carrier's rates,'' and that the phrase may encompass other charges and surcharges, such as tariff rates for empty tank car movements and fuel surcharges. (NGFA Comment 4.) The Board clarifies that the term ''rate disputes'' entails challenges to the reasonableness of a rail carrier's whole line-haul rate, which may include other charges, such as fuel surcharges, in addition to the base rate. *See, e.g., N. Am. Freight Car Ass'n* v. *BNSF Ry.,* NOR 42060 (Sub-No. 1), slip op. at 7 (STB served Jan. 26, 2007) (rate reasonableness refers to the ''total amount paid'' in the line-haul rate). A challenge to a tariff rate for empty car movements would be a ''rate dispute.'' Parties may voluntarily agree to arbitrate other matters under § 1108.4(e), such as the application of a specific charge or fuel surcharge that would not constitute a ''rate dispute,'' but such disputes would be subject to the monetary award cap of $2,000,000 for non-rate cases.

Other Items to Address or Clarify. NGFA recommends that the Board define ''accessorial charges,'' which are listed as matters eligible for arbitration under section 11708 and the proposed rules at § 1108.1(d) and (j). (NGFA Comment 5.) The Board clarifies here that accessorial charges may include, but are not limited to, charges for diversion, inspection, reconsignment, storing, weighing, and other services not specified in the statute and § 1108.1(d) and (j).

Several shippers suggest that the Board maintain a record of unsuccessful attempts to arbitrate disputes, so that if the arbitration system is not well utilized, the record would help the Board understand why the arbitration system is not being used. (ACC Comment 2; RCC Comment 2; NGFA Comment 4.) Given that arbitration is voluntary under these rules, the Board declines to keep a record of unsuccessful attempts to arbitrate. A record of unsuccessful attempts to arbitrate would not necessarily provide useful guidance to the Board, given the wide variety of valid reasons why a party may decline to arbitrate a given dispute.

NGFA recommends that the proposed rules be revised to expressly state that the Board's arbitration rules do not preempt the applicability of, or otherwise supersede, existing industry-operated arbitration systems. (NGFA Comment 8.) The Board's current regulations at § 1108.2(a)(2) provide that ''nothing in these rules shall be construed in a manner to prevent parties from independently seeking or utilizing private arbitration services to resolve any disputes they may have.'' Nothing in the rules we adopt here changes that aspect of the existing rules.

SMART/TD–NY requests that the Board allow third parties, such as labor parties, to intervene in arbitration proceedings. (SMART/TD–NY Comment 7.) As the Board noted in *Arbitration of Certain Disputes Subject to the Statutory Jurisdiction of the Surface Transportation Board,* 2 S.T.B. 564, 574 (1997), a central objective of arbitration is to avoid a formal regulatory proceeding, and allowing the participation of uninvited third parties would contravene the voluntary and informal nature of the arbitration process. Accordingly, the Board denies SMART/TD–NY's request to allow for third-party intervention in arbitration proceedings.

Lastly, SMART/TD–NY states that the labor arbitration standard in 49 CFR 1115.8 should be deleted because labor disputes are not eligible for arbitration. (SMART/TD–NY Comment 9.) Under 49 U.S.C. 11708(b)(2)(C), the Board's arbitration procedures do not apply to disputes ''to enforce a labor protective condition.'' But it is well settled that the Board can delegate authority to arbitrators to adjudicate disputes—subject to Board review—over the appropriate conditions to impose to protect affected employees. *Ass'n of Am. R.R.s* v. *STB,* 162 F.3d 101, 107 (D.C. Cir. 1998). Accordingly, the Board clarifies here that § 1115.8 reflects both the standard of review used by the Board for arbitrations conducted pursuant to 49 CFR part 1108 and the standard of review for labor arbitration cases to resolve disputes involving employee protection conditions. In Docket No. 699, the Board inadvertently omitted the standard of review for labor arbitration cases in § 1115.8. In the NPR, the Board properly proposed to correct this omission.

The final rules are set forth below.

Regulatory Flexibility Act. The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, generally requires a description and analysis of new rules that would have a significant economic impact on a substantial number of small entities. In drafting a rule, an agency is required to: (1) Assess the effect that its regulation will have on small entities; (2) analyze effective alternatives that may minimize a regulation's impact; and (3) make the analysis available for public comment. 5 U.S.C. 601–604. Under section 605(b), an agency is not required to perform an initial or final regulatory flexibility analysis if it certifies that the proposed or final rules will not have a ''significant impact on a substantial number of small entities.''

Because the goal of the RFA is to reduce the cost to small entities of complying with federal regulations, the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates those entities. In other words, the impact must be a direct impact on small entities ''whose conduct is circumscribed or mandated'' by the proposed rule. *White Eagle Coop. Ass'n* v. *Conner,* 553 F.3d 467, 478, 480 (7th Cir. 2009). An agency has no obligation to conduct a small entity impact analysis of effects on entities that it does not regulate. *United Distrib. Cos.* v. *FERC,* 88 F.3d 1105, 1170 (D.C. Cir. 1996).

In the NPR, the Board already certified under 5 U.S.C. 605(b) that the proposed rules would not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. The Board explained that the proposed rules would not place any additional burden on small entities, but rather amend the existing procedures for arbitrating disputes before the Board. The Board further explained that, although some carriers and shippers impacted by the proposed rules may qualify as a ''small business'' within the meaning of 5 U.S.C. 601(3), it did not anticipate that the revised arbitration procedures would have a significant economic impact on a large number of small entities. The Board noted that, to the extent that the rules have any impact, it would be to provide faster resolution of a controversy at a lower cost. Moreover, the Board noted that the relief that could be accorded by an arbitrator would presumably be similar to the relief shippers could obtain through use of the Board's existing formal adjudicatory procedures, and at a greater net value considering that the arbitration process is designed to consume less time and likely will be less costly. A copy of the NPR was served on the U.S. Small Business Administration (SBA).

The final rules adopted here make slight modifications to the proposed rules. However, the same basis for the Board's certification of the proposed rules apply to the final rules adopted here. The final rules will not create a significant impact on a substantial number of small entities. The modifications adopted in the final rules refine the proposed arbitration process and clarify the existing regulations. Therefore, the Board certifies under 5 U.S.C. 605(b) that the final rules will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. A copy of this decision will be served upon the Chief Counsel for Advocacy, Office of Advocacy, U.S. Small Business Administration, Washington, DC 20416.

Paperwork Reduction Act. In the NPR, the Board sought comments pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3549, and Office of Management and Budget (OMB) regulations at 5 CFR 1320.11 regarding: (1) Whether the collection of information associated with the proposed arbitration program is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility; (2) the accuracy of the Board's burden estimates; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology, when

appropriate. No comments were received pertaining to the collection of this information under the PRA.

The proposed collection was submitted to OMB for review as required under the PRA, 44 U.S.C. 3507(d), and 5 CFR 1320.11. OMB is withholding approval pending submission of the final rules. Simultaneously with publishing these final rules, we are submitting the final rules to OMB for approval. Once approval is received, OMB will issue a collection control number (2140–XXXX), and we will publish a notice in the **Federal Register**. Until renewed, OMB approval of this collection is expected to expire October 30, 2019. Under the PRA and 5 CFR 1320.11, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number. As required, simultaneously with the publication of these final rules, the Board is submitting this modified collection to OMB for review.

List of Subjects

49 CFR Part 1108

Administrative practice and procedure, Railroads.

49 CFR Part 1115

Administrative practice and procedure.

It is ordered:

1. The Board adopts the final rules as set forth in this decision. Notice of the adopted rules will be published in the **Federal Register**.

2. This decision is effective 30 days after the day of service.

Decided: September 28, 2016.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman.

Kenyatta Clay,

Clearance Clerk.

For the reasons set forth in the preamble, under the authority of 49 U.S.C. 1321, title 49, chapter X, parts 1108 and 1115 of the Code of Federal Regulations are amended as follows:

PART 1108—ARBITRATION OF CERTAIN DISPUTES SUBJECT TO THE STATUTORY JURISDICTION OF THE SURFACE TRANSPORTATION BOARD

■ 1. Revise the authority citation for part 1108 to read as follows:

Authority: 49 U.S.C. 11708, 49 U.S.C. 1321(a), and 5 U.S.C. 571 *et seq.*

■ 2. Amend § 1108.1 as follows:

■ a. In paragraph (b), add the words ''from the roster'' after the word ''selected'' and remove the word ''neutral'' and add in its place ''lead''.

■ b. In paragraph (d), add ''rates;'' after ''subjects:''.

■ c. In paragraph (g), add the words ''and the Surface Transportation Board Reauthorization Act of 2015'' after ''1995''.

■ d. Revise paragraphs (h) and (i).

■ e. Redesignate paragraphs (j) and (k) as paragraphs (k) and (l).

■ f. Add a new paragraph (j) and paragraph (m).

The revisions and additions read as follows:

§ 1108.1 Definitions.

* * * * *

(h) *Lead arbitrator or single arbitrator* means the arbitrator selected by the strike methodology outlined in § 1108.6(c).

(i) *Monetary award cap* means a limit on awardable damages of $25,000,000 in rate disputes, including any rate prescription, and $2,000,000 in practice disputes, unless the parties mutually agree to a lower award cap. If parties bring one or more counterclaims, such counterclaims will be subject to a separate monetary award cap.

(j) *Practice disputes* are disputes involving demurrage; accessorial charges; misrouting or mishandling of rail cars; and disputes involving a carrier's published rules and practices as applied to particular rail transportation.

* * * * *

(m) *Rate disputes* are disputes involving the reasonableness of a rail carrier's rates.

■ 3. Amend § 1108.2 as follows:

■ a. In paragraph (a) introductory text, remove ''$200,000'' and add in its place ''$25,000,000 in rate disputes, including any rate prescription, and $2,000,000 in other disputes'' and remove the word ''different'' and add in its place ''lower''.

■ b. In paragraph (a)(1), remove the word ''different'' and add in its place ''lower''.

■ c. Revise paragraph (b).

The revision reads as follows:

§ 1108.2 Statement of purpose, organization, and jurisdiction.

* * * * *

(b) *Limitations to the Board's arbitration program.* These procedures shall not be available:

(1) To resolve disputes involving labor protective conditions;

(2) To obtain the grant, denial, stay or revocation of any license, authorization (*e.g.,* construction, abandonment, purchase, trackage rights, merger, pooling), or exemption related to such matters;

(3) To prescribe for the future any conduct, rules, or results of general, industry-wide applicability;

(4) To resolve disputes that are solely between two or more rail carriers.

Parties may only use these arbitration procedures to arbitrate matters within the statutory jurisdiction of the Board.

■ 4. Amend § 1108.3 as follows:

■ a. In paragraph (a) introductory text, remove the word ''either''.

■ b. In paragraph (a)(1)(ii), remove the words ''different monetary award cap'' and add in their place ''lower monetary award cap than the monetary award caps provided in this part''.

■ c. Revise paragraph (a)(2).

■ d. Remove paragraph (a)(2)(i).

■ e. Add paragraph (a)(3).

■ f. In paragraph (b), add ''itself'' after ''not'' and remove ''within that'' and add in its place ''prior to the end of the''.

■ g. In paragraph (c), remove ''on a case-by-case basis'' and add in its place ''only for a particular dispute''.

The revision and addition read as follows:

§ 1108.3 Participation in the Board's arbitration program.

* * * * *

(a) * * *

(2) Participants to a proceeding, where one or both parties have not opted into the arbitration program, may by joint notice agree to submit an issue in dispute to the Board's arbitration program. The joint notice must clearly state the issue(s) which the parties are willing to submit to arbitration and the corresponding maximum monetary award cap if the parties desire to arbitrate for a lower amount than the monetary award cap that would otherwise be applicable.

(3) Parties to a dispute may jointly notify the Board that they agree to submit an eligible matter in dispute to the Board's arbitration program, where no formal proceeding has begun before the Board. The joint notice must clearly state the issue(s) which the parties are willing to submit to arbitration and the corresponding maximum monetary award cap if the parties desire to arbitrate for a lower amount than the applicable monetary award cap.

* * * * *

■ 5. Amend § 1108.4 as follows:

■ a. In paragraph (a), add ''rates;'' before the word ''Demurrage''.

■ b. In paragraph (b) introductory text, remove ''may not exceed'' and add in its place ''will be subject to''; remove ''$200,000'' and add in its place ''$25,000,000, including any rate prescription,''; and remove ''arbitral

proceeding'' and add in its place ''rate dispute and $2,000,000 per practice dispute''.

■ c. In paragraphs (b)(1) and (2), remove the word ''different'' and add in its place ''lower''.

■ d. In paragraph (b)(3), remove ''$200,000'' and add in its place ''$25,000,000, including any rate prescription,''; remove ''case'' and add in its place ''rate dispute and $2,000,000 per practice dispute''; and remove ''different'' and add in its place ''lower''.

■ f. In paragraph (c), remove the words ''arising in a docketed proceeding'' and add ''for a particular dispute'' after ''consent to arbitration''.

■ g. In paragraph (e), add a sentence after the second sentence and remove ''which'' and add in its place ''that''.

■ h. Add paragraph (g).

The revision and additions read as follows:

§ 1108.4 Use of arbitration.

* * * * *

(e) * * * Such disputes are subject to a monetary award cap of $2,000,000 or to a lower cap agreed upon by the parties in accordance with paragraph (b)(2) of this section.* * *

* * * * *

(g) *Rate disputes.* Arbitration of rate disputes will only be available to parties if the rail carrier has market dominance as determined by the Board under 49 U.S.C. 10707. In rate disputes, the arbitrator or panel of arbitrators, as applicable, shall consider the Board's methodologies for setting maximum lawful rates, giving due consideration to the need for differential pricing to permit a rail carrier to collect adequate revenues (as determined under 49 U.S.C. 10704(a)(2)).

■ 6. Amend § 1108.5 as follows:

■ a. In paragraph (a) introductory text, add ''Except as provided in paragraph (e) of this section,'' to the beginning of the first sentence and remove ''Arbitration'' and add in its place ''arbitration''.

■ b. In paragraph (a)(1), remove the word ''single-neutral'' and add in its place ''single''.

■ c. In paragraph (a)(3), remove the word ''different'' and add in its place ''lower''; remove ''$200,000''; and add ''that would otherwise apply'' after ''cap''.

■ d. In paragraph (b)(1) introductory text, remove the word ''single-neutral'' and add in its place ''single'' wherever it appears and remove the words ''the request'' and add in their place ''that request''.

■ f. In paragraph (b)(1)(i), remove the word ''single-neutral'' and add in its place ''single''.

■ g. In paragraph (b)(1)(ii), remove the word ''single-neutral'' and add in its place ''single'' wherever it appears; remove ''§ 1108.6(a)–(c)'' and add in its place ''§ 1108.6(a) through (d)''; remove the word ''matter'' and add in its place ''case''; and add ''by the Board'' after ''adjudication''.

■ h. Revise paragraph (b)(2).

■ i. In paragraph (b)(3), remove the word ''different'' and add in its place ''lower'' and remove ''$200,000'' and add in its place ''otherwise applicable''.

■ j. Revise paragraph (e).

■ k. Add paragraphs (f) and (g).

The revisions and additions read as follows:

§ 1108.5 Arbitration commencement procedures.

* * * * *

(b) * * *

(2) When the complaint limits the arbitrable issues, the answer must state whether the respondent agrees to those limitations or, if the respondent is already a participant in the Board's arbitration program, whether those limitations are consistent with the respondent's opt-in notice filed with the Board pursuant to § 1108.3(a)(1)(i). If the answer contains an agreement to arbitrate some but not all of the arbitration-program-eligible issues in the complaint, the complainant will have 10 days from the date of the answer to advise the respondent and the Board in writing whether the complainant is willing to arbitrate on that basis.

* * * * *

(e) *Jointly-filed notice.* In lieu of a formal complaint proceeding, arbitration under these rules may commence with a jointly-filed notice by parties agreeing to submit an eligible matter in dispute to the Board's arbitration program under § 1108.3(a)(3). The notice must:

(1) Contain a statement that all relevant parties are participants in the Board's arbitration program pursuant to § 1108.3(a), or that the relevant parties are willing to arbitrate voluntarily a matter pursuant to the Board's arbitration procedures, and the relief requested;

(2) Indicate whether parties have agreed to a three-member arbitration panel or a single arbitrator;

(3) Indicate if the parties have agreed to a lower amount of potential liability in lieu of the otherwise applicable monetary award cap.

(f) *Arbitration initiation.* When the parties have agreed upon whether to use a single arbitrator or a panel of arbitrators, the issues(s) to be arbitrated, and the monetary limit to any arbitral decision, the Board shall initiate the arbitration under § 1108.7(a) and provide a list of arbitrators as described in § 1108.6.

(g) *Arbitration agreement.* Shortly after the panel of arbitrators or arbitrator is selected, the parties to arbitration together with the lead or single arbitrator, as applicable, shall create a written arbitration agreement, which at a minimum will state with specificity the issues to be arbitrated and the corresponding monetary award cap to which the parties have agreed. The agreement may also contain other mutually agreed upon provisions.

(1) Any additional issues selected for arbitration by the parties, that are not outside the scope of these arbitration rules as explained in § 1108.2(b), must be subject to the Board's statutory authority.

(2) These rules shall be incorporated by reference into any arbitration agreement conducted pursuant to an arbitration complaint filed with the Board.

■ 7. Amend § 1108.6 as follows:

■ a. In paragraph (a), remove ''§ 1108.5(a)(1)'' and add in its place ''§ 1108.5(a)(1) and agreed to by all parties to the arbitration''.

■ b. Revise paragraph (b).

■ c. Revise paragraph (c) introductory text.

■ d. In paragraph (c)(1), remove the word ''neutral'' wherever it appears and in the second sentence add ''lead'' in its place.

■ e. Revise paragraph (c)(2).

■ f. Remove paragraph (c)(3).

■ g. Revise paragraph (d).

■ h. Redesignate paragraph (e) as paragraph (f).

■ i. Add a new paragraph (e).

■ j. In newly redesignated paragraph (f)(1), remove ''§ 1108.6(b)'' and add in its place ''§ 1108.6(d)''.

■ k. Revise newly redesignated paragraph (f)(2).

The revisions and addition read as follows:

§ 1108.6 Arbitrators.

* * * * *

(b) *Roster.* Arbitration shall be conducted by an arbitrator (or panel of arbitrators) selected, as provided herein, from a roster of persons with rail transportation, economic regulation, professional or business experience, including agriculture, in the private sector. Persons seeking to be included on the roster must have training in dispute resolution and/or experience in arbitration or other forms of dispute resolution. The Board will establish the initial roster of arbitrators by no-objection vote. The Board may modify

the roster at any time by no-objection vote to include other eligible arbitrators or remove arbitrators who are no longer available. The Board's roster will provide a brief biographical sketch of each arbitrator, including information such as background, area(s) of expertise, arbitration experience, and geographical location, as well as general contact information and fees, based on the information supplied by the arbitrator. The roster shall be published on the Board's Web site. The Board will update the roster every year. The Board will seek public comment on any modifications that should be made to the roster, including requesting the names and qualifications of new arbitrators who wish to be placed on the roster, and updates from arbitrators appearing on the roster to confirm that the biographical information on file with the Board remains accurate. Arbitrators who wish to remain on the roster must notify the Board of their continued availability.

(c) *Selecting the lead arbitrator.* If the parties cannot mutually agree on a lead arbitrator for a panel of arbitrators, the parties shall use the following process to select a lead arbitrator: First, each party will be given three peremptory strikes to remove names from the Board's roster. Then, from the remaining names on the roster, each party will submit a list of up to 10 potential arbitrators. If only one arbitrator appears on both lists, he or she would be selected as the single or lead arbitrator. If multiple arbitrators appear on both lists, the parties would alternatively strike names of the jointly listed arbitrators until one remains, beginning with complainant. If no name appears on both lists, the parties would alternatively strike from the Board's entire roster, as amended based on the peremptory strikes. A lead arbitrator shall be selected within 14 days of the Board initiating the arbitration process.

* * * * *

(2) The lead arbitrator appointed through the strike methodology shall serve as the head of the arbitration panel and will be responsible for ensuring that the tasks detailed in §§ 1108.7 and 1108.9 are accomplished.

(d) *Party-appointed arbitrators.* The party or parties on each side of an arbitration dispute shall select one arbitrator from the roster, regardless of whether the other party struck the arbitrator's name in selecting a lead arbitrator. The party or parties on each side will appoint that side's own arbitrator within 14 days of the Board initiating the arbitration process. Parties on one side of an arbitration proceeding may not challenge the arbitrator selected by the opposing side.

(e) *Use of a single arbitrator.* Parties to arbitration may request the use of a single arbitrator. Requests for use of a single arbitrator must be included in a complaint or an answer as required in § 1108.5(a)(1), or in the joint notice filed under § 1108.5(e). Parties to both sides of an arbitration dispute must agree to the use of a single arbitrator in writing. If the single-arbitrator option is selected, and if parties cannot mutually agree on a single arbitrator, the arbitrator selection procedures outlined in paragraph (c) of this section shall apply.

(f) * * *

(2) If the incapacitated arbitrator was the lead or single arbitrator, the parties shall promptly inform the Board of the arbitrator's incapacitation and the selection procedures set forth in paragraph (c) of this section shall apply.

■ 8. Revise § 1108.7 to read as follows:

§ 1108.7 Arbitration procedures.

(a) *Initiation.* With the exception of rate dispute arbitration proceedings, the Board shall initiate the arbitration process within 40 days after submission of a written complaint or joint notice filed under § 1108.5(e). In arbitrations involving rate disputes, the Board shall initiate the arbitration process within 10 days after the Board issues a decision determining that the rail carrier has market dominance.

(b) *Arbitration evidentiary phase timetable.* Whether the parties select a single arbitrator or a panel of three arbitrators, the lead or single arbitrator shall establish all rules deemed necessary for each arbitration proceeding, including with regard to discovery, the submission of evidence, and the treatment of confidential information, subject to the requirement that this evidentiary phase shall be completed within 90 days from the date on which the arbitration process is initiated, unless a party requests an extension, and the arbitrator or panel of arbitrators, as applicable, grants such extension request.

(c) *Written decision timetable.* The lead or single arbitrator will be responsible for writing the arbitration decision. The unredacted arbitration decision must be served on the parties within 30 days of completion of the evidentiary phase. A redacted copy of the arbitration decision must be served upon the Board within 60 days of the close of the evidentiary phase for publication on the Board's Web site.

(d) *Extensions to the arbitration timetable.* The Board may extend any deadlines in the arbitration timetable provided in this part upon agreement of all parties to the dispute.

(e) *Protective orders.* Any party, on either side of an arbitration proceeding, may request that discovery and the submission of evidence be conducted pursuant to a standard protective order agreement.

■ 9. Amend § 1108.8 by revising paragraph (a) to read as follows:

§ 1108.8 Relief.

(a) *Relief available.* An arbitrator may grant relief in the form of monetary damages or a rate prescription in rate disputes to the extent they are available under this part or as agreed to in writing by the parties. A rate prescription shall not exceed 5 years.

* * * * *

■ 10. Amend § 1108.9 as follows:

■ a. Revise paragraph (a).

■ b. In paragraph (b), remove the word ''neutral'' and add in its place ''lead or single''.

■ c. In paragraph (d), remove the heading ''*Neutral arbitrator authority''* and add in its place ''*Lead or single arbitrator authority'';* remove the word ''neutral'' from the first sentence and add in its place ''lead or single''; and add '', if any,'' after ''what''.

■ d. In paragraph (e), remove the word ''neutral'' wherever it appears and add in its places ''lead or single'' and remove ''§ 1108.7(b)'' and add in its place ''§ 1108.7(c)''.

■ e. In paragraph (f), remove the word ''neutral'' and add in its place ''lead or single''.

The revision reads as follows:

§ 1108.9 Decisions.

(a) *Decision requirements.* Whether by a panel of arbitrators or a single arbitrator, all arbitration decisions shall be in writing and shall contain findings of fact and conclusions of law. All arbitration decisions must be consistent with sound principles of rail regulation economics. The arbitrator shall provide an unredacted draft of the arbitration decision to the parties to the dispute, in accordance with any protective order governing the release of confidential and highly confidential information pursuant to § 1108.7(e).

* * * * *

■ 11. Amend § 1108.11 as follows:

■ a. In paragraph (a), add ''upon the Board'' after ''20 days of service''.

■ b. Revise paragraph (b) introductory text.

The revision reads as follows:

§ 1108.11 Enforcement and appeals.

* * * * *

(b) *Board's standard of review.* On appeal, the Board's standard of review

of arbitration decisions will be narrow. The Board will review a decision to determine if the decision is consistent with sound principles of rail regulation economics, a clear abuse of arbitral authority or discretion occurred; the decision directly contravenes statutory authority; or the award limitation was violated. Using this standard, the Board may modify or vacate an arbitration award in whole or in part.

* * * * *

■ 12. Amend § 1108.12 as follows:
■ a. Revise paragraph (b).
■ b. Remove paragraphs (c) and (d).
The revision reads as follows:

§ 1108.12 Fees and costs.

* * * * *

(b) *Costs.* The parties shall share the costs incurred by the Board and arbitrators equally, with each party responsible for paying its own legal and other associated arbitration costs.

PART 1115—APPELLATE PROCEDURES

■ 13. The authority citation for part 1115 is revised to read as follows:

Authority: 5 U.S.C. 559; 49 U.S.C. 1321; 49 U.S.C. 11708.

■ 14. Revise § 1115.8 to read as follows:

§ 1115.8 Petitions to review arbitration decisions.

An appeal of right to the Board is permitted. The appeal must be filed within 20 days upon the Board of a final arbitration decision, unless a later date is authorized by the Board, and is subject to the page limitations of § 1115.2(d). For arbitrations authorized under part 1108 of this chapter, the Board's standard of review of arbitration decisions will be narrow, and relief will only be granted on grounds that the decision is inconsistent with sound principles of rail regulation economics, a clear abuse of arbitral authority or discretion occurred, the decision directly contravenes statutory authority, or the award limitation was violated. For labor arbitration decisions, the Board's standard of review is set forth in *Chicago and North Western Transportation Company—Abandonment—near Dubuque & Oelwein, Iowa,* 3 I.C.C.2d 729 (1987), *aff'd sub nom. International Brotherhood of Electrical Workers* v. *Interstate Commerce Commission,* 862 F.2d 330 (D.C. Cir. 1988). The timely filing of a petition will not automatically stay the effect of the arbitration decision. A stay may be requested under § 1115.3(f).

[FR Doc. 2016–24065 Filed 10–5–16; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2015–0142; 4500030113]

RIN 1018–BB09

Endangered and Threatened Wildlife and Plants; Threatened Species Status for Suwannee Moccasinshell

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine threatened species status under the Endangered Species Act of 1973 (Act), as amended, for the Suwannee moccasinshell (*Medionidus walkeri*), a freshwater mussel species from the Suwannee River Basin in Florida and Georgia. The effect of this regulation will be to add this species to the List of Endangered and Threatened Wildlife.

DATES: This rule becomes effective November 7, 2016.

ADDRESSES: This final rule is available on the internet at *http://www.regulations.gov* at Docket No. FWS–R4–ES–2015–0142 and the Panama City Ecological Services Field Office. Comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *http://www.regulations.gov.* Comments, materials, and documentation that we considered in this rulemaking will be available by appointment, during normal business hours at: U.S. Fish and Wildlife Service, Panama City Ecological Services Field Office, 1601 Balboa Avenue, Panama City, FL 32405; by telephone 850–769–0552; or by facsimile at 850–763–2177.

FOR FURTHER INFORMATION CONTACT: Catherine T. Phillips, Project Leader, U.S. Fish and Wildlife Service, Panama City Ecological Services Field Office, 1601 Balboa Avenue, Panama City, FL 32405; by telephone 850–769–0552; or by facsimile at 850–763–2177. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act (Act), a species may require protection through listing if it is endangered or threatened throughout all or a significant portion of its range. Listing a species as an endangered or threatened species can only be completed by issuing a rule.

What this document does. This rule will finalize the listing of the Suwannee moccasinshell (*Medionidus walkeri*) as a threatened species. In the near future, we intend to publish a proposed rule in the **Federal Register** to designate critical habitat for the Suwannee moccasinshell under the Act.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the Suwannee moccasinshell is threatened by the degradation of its habitat due to polluted runoff from agricultural lands, pollutants discharged or accidentally released from industrial and municipal wastewater sources and mining operations, decreased flows due to groundwater extraction and drought, stream channel instability, and excessive sedimentation (Factor A); State and Federal water quality standards that are inadequate to protect sensitive aquatic organisms like mussels (Factor D); the potential of contaminant spills as a result of transportation accidents (Factor E); increased drought frequency and degraded water quality as a result of changing climatic conditions (Factor E); greater vulnerability to certain threats because of small population size and range (Factor E); and competition and disturbance from the introduced Asian clam (Factor E).

Peer review and public comment. We sought comments from independent specialists to ensure that our listing rule is based on scientifically sound data, assumptions, and analyses. We invited three peer reviewers with expertise in Suwannee moccasinshell biology and ecology, and freshwater mussel biology and conservation, to comment on our listing proposal. We also considered all other comments and information received during the public comment period. All comments and information received are available on the internet at *http://www.regulations.gov* in Docket *No.* FWS–R4–ES–2015–0142.

Previous Federal Action

Please refer to the proposed listing rule for the Suwannee moccasinshell

(80 FR 60335; October 6, 2015) for a detailed description of previous Federal actions concerning this species.

Background

For a more detailed discussion of the biology, status, and threats affecting the species, please refer to the proposed listing rule for the Suwannee moccasinshell published in the **Federal Register** on October 6, 2015 (80 FR 60335). In the proposed rule, we evaluated the biological status of the species and factors affecting its continued existence. Our assessment was based upon the best available scientific and commercial data available on the status of the species, including past, present, and future threats to the species.

Summary of Comments and Recommendations

In the proposed rule published on October 6, 2015 (80 FR 60335), we requested that all interested parties submit written comments on the proposal by December 7, 2015. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. Newspaper notices inviting general public comment were published in The Lake City Reporter, Columbia County, FL; The Gainesville Sun, Alachua County, FL; and The Valdosta Daily Times, Lowndes County, GA. During the public comment period, we received public comments from 11 individuals or organizations, including 3 submissions by the individuals asked to serve as peer reviewers. We did not receive any requests for a public hearing. All substantive information provided during the comment period is summarized below in the Summary of Changes From the Proposed Rule and has either been incorporated directly into this final determination or addressed in the more specific response to comments below.

Comments From Peer Reviewers

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinion from three knowledgeable individuals with scientific expertise in the species' biology, habitat, and threats and stream ecology. We received responses from all of the peer reviewers.

We reviewed all comments from the peer reviewers for substantive issues and new information regarding the listing of the Suwannee moccasinshell. In general, the peer reviewers concurred with our methods and conclusions. Where appropriate, we incorporated new information into the final rule as a result of the peer reviewer comments, and any substantive comments are discussed below.

(1) Comment: One peer reviewer expressed concern that there has been no modern taxonomic study to assess whether the Suwannee moccasinshell is a distinct species from the Gulf moccasinshell. The peer reviewer mentioned that shell morphological traits are notoriously problematic taxonomic features that have led to the misclassification of many freshwater mussel taxa, and that only with molecular data can you be reasonably sure that you are dealing with separate species. The reviewer also added that there was no reason to suspect that the Suwannee moccasinshell is not a valid species.

Our Response: We relied on the best information currently available regarding the taxonomy of the species. The Suwannee moccasinshell is considered a distinct taxonomic entity by the general scientific community, and we are aware of no contradicting views on the taxonomy of this entity. However, in the final rule we have refined our discussion of the species' taxonomy and added a recent publication by Johnson *et al.* (in press) to the list of authors who recognize the entity as a separate species.

(2) Comment: One peer reviewer expressed concerned about the lack of surveys in the Withlacoochee drainage, and stated that this stream still supports large populations of freshwater mussels. The reviewer stated that there has apparently been very little recent work in the system, and that intensive surveys should be done in the Withlacoochee Drainage to determine the status of the Suwannee moccasinshell in this system.

Our Response: We agree and stated in the proposed rule that additional survey work is needed in the Withlacoochee River subbasin (80 FR 60335, October 6, 2015; p. 60338). Since publishing the proposed rule, some additional surveys were conducted in the lower Withlacoochee drainage. Those surveys are included in Table 2 below. Surveyors using snorkel gear searched seven locations in the lower basin in September 2015. Several mussel species were detected, but not Suwannee moccasinshell. Likely contributing factors for non-detection include the conditions noted at survey locations within this species' historical range, including an odor of treated sewage and considerable amounts of filamentous algae (an indicator of excess nutrients).

Also, since the proposed rule was published, the Service's Panama City Field Office received two reports of mussel surveys conducted in 2005 and 2007 around the State Road 31 Bridge in Georgia, where the Suwannee moccasinshell was collected in 1969. Comprehensive surveys were conducted over several days using SCUBA gear to search a 1.5-kilometer reach (approximately) of the Withlacoochee River (Bowers 2006, entire; Bowers 2007, entire). The species was not detected during these dive surveys. These additional data support our conclusion that the Suwannee moccasinshell may no longer occur in the Withlacoochee subbasin.

(3) Comment: One peer reviewer commented that spate flows (*e.g.,* sudden fast flows with high sediment loads) in the upper Santa Fe River should be listed as a threat.

Our Response: We agree and have added this threat to the Factor A discussion under the heading of *Stream Channel Instability.*

(4) Comment: One peer reviewer commented that deadhead logging, though probably past its heyday, is still a potential threat to the Suwannee moccasinshell as it can cause destabilization of microhabitat occupied by freshwater mussels. The peer reviewer also stated that the impact of constant and, in many cases, large boat wakes frequently striking shore is a problem, especially in the lower Santa Fe River, which is a relatively narrow channel frequented by large numbers of boats.

Our Response: We appreciate this information, and we have added a discussion of both activities to the Factor A discussion under the heading of *Stream Channel Instability.*

(5) Comment: One peer reviewer suggested deleting flathead catfish as a potential threat. The reviewer pointed out that there is only one record from the Suwannee River of flathead catfish, which was collected near Branford in 1989, and the species is not currently considered to be extant in the basin. The reviewer believed that flathead catfish may represent a future threat if they ever become successfully established in the basin.

Our Response: Based on this information, we agree that flathead catfish are not a significant concern at this time and have deleted the discussion from the final rule.

Comments From States

The proposed rule was reviewed by the three members of the Florida Fish and Wildlife Conservation Commission's (FWC) freshwater mussel conservation program, one of which was asked to serve as a peer reviewer. The

comments were combined into one document and submitted as a single peer review. The FWC reviewers provided additional information and clarification on threats, and provided updated information on surveys conducted by the agency. Their comments are addressed in Comments 3, 4, and 5 above, and are incorporated into the final rule as appropriate. The FWC generally concurred with our methods and conclusions, and supports the listing.

We also received comments from the Florida Department of Transportation (FDOT). They are addressed below.

(6) Comment: The FDOT expressed concern about our use of the term ''transportation accidents'' with regard to possible contamination spills. The agency stated that transportation agencies have protocols in place to address and track these spills.

Our Response: We continue to maintain that accidents involving vehicles transporting large volumes of hazardous materials are a potential threat to the Suwannee moccasinshell. Accidental spills of hazardous materials or organic materials into streams as a result of transportation accidents have occurred in the past. Incidents in or near streams that illustrate the potential risk include two train derailments: one on September 12, 2006, that spilled four tank cars of soybeans into a tributary of Yellow Leaf Creek in Alabama resulting in a drastic decline in dissolved oxygen, killing fishes, mussels, and snails (USFWS 2009); and another on January 28, 2014, that spilled up to 30,000 gallons of phosphoric acid into a small tributary to the Escambia River in Florida (*NorthEscambia.com*), and was contained before reaching critical habitat in the mainstem.

(7) Comment: The FDOT expressed concerns regarding our discussion of water quality degradation and increased sedimentation. The agency commented that State DOTs abide by rigorous environmental permit processes (both Federal and State) that address these matters including requirements of the ESA. Specifically, roadway projects have to obtain a State Water Quality Certification in order for the U.S. Army Corps to issue a permit under section 404 of the Clean Water Act.

Our Response: FDOT's standard Best Management Practices (BMPs) for erosion and sediment control are a good baseline measure to protect water quality. However, the success of these measures is highly dependent on their contractors to meticulously implement, monitor, and repair erosion control measures. In instances where endangered and threatened species are present in combination with highly erodible soils, a higher level of protection may be needed. While not frequent, instances of erosion control failures that have impacted waterways during road construction in Florida have been documented.

(8) Comment: The FDOT commented that the following activities listed in the proposed rule (80 FR 60335, October 6, 2015; p. 60347) as potentially harming the Suwannee moccasinshell and, therefore, resulting in take, could impact State DOT projects: destruction or alteration of the species' habitat by discharge of fill material; dredging or modification of stream channels or banks; and discharge of pollutants into a stream or into areas hydrologically connected to a stream occupied by the species.

Our Response: The majority of the stream channels currently occupied by the Suwannee moccasinshell, including the Suwannee River mainstem and the lower Withlacoochee River, are also occupied by, or designated as critical habitat for, the federally threatened Gulf sturgeon. The lower Santa Fe River is the only area occupied by Suwannee moccasinshell, but not by Gulf sturgeon. Therefore, because activities that affect the Suwannee moccasinshell would also affect the Gulf sturgeon or its habitat (for example, dredging, filling, modification of stream channels or banks, and discharge of pollutants), in the majority of the Suwannee moccasinshell's current range, the FDOT already consults on such activities. When formal section 7 consultation is required, we will work with the FDOT to find solutions that will reduce impacts to all listed species and aquatic habitats, while allowing the activity to proceed.

Public Comments

(9) Comment: One commenter expressed concern about our finding that forestry is a contributing threat to the Suwannee moccasinshell. The commenter provided information on the implementation rates and effectiveness of forestry BMPs and cited various studies purported to demonstrate that forestry BMPs minimize erosion and sediment transport to streams below levels that degrade aquatic habitats and/or harm aquatic species, including the Suwannee moccasinshell.

Response: We appreciate the commenters' support of forestry BMPs as a means of protecting water quality and we concur that, when properly implemented, forestry BMPs can reduce erosion and sedimentation levels, especially as compared to past forestry practices. However, the best available data indicate that, even when forestry BMPs are properly implemented, erosion rates at harvested sites, skid trails, unpaved haul roads, and stream crossings are significantly higher than from undisturbed sites. We consider sediment from silvicultural activities to be one of many potential sediment sources within the Suwannee River watershed.

Summary of Changes From the Proposed Rule

After consideration of the comments we received during the public comment period (refer to Summary of Comments and Recommendations above), and new information published or obtained since the proposed rule was published, we made changes to the final listing rule. Many small, nonsubstantive changes and corrections, not affecting the determination (*e.g.,* updating the Background section in response to comments, minor clarifications) were made throughout the document. Below is a summary of substantive changes made to the final rule.

(1) The *Taxonomy* discussion was refined slightly. The distinctiveness of Suwannee moccasinshell as a separate species was further bolstered by a recent study (Johnson *et al.* in Press).

(2) Table 2 was added to provide a clear and updated summary of all recent survey information.

(3) The flathead catfish (*Pylodictis olivaris*) was removed as a threat to reflect information provided by the Florida FWC indicating that flathead catfish have not become established in the Suwannee River Basin.

(4) *Stream Channel Instability* was added as a threat under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range.* The new discussion adds threats identified by a peer reviewer that include scouring flows, boat wakes, and deadhead logging.

Summary of Biological Status

Below we present a summary of the biological and distributional information discussed in the proposed listing rule. We also present new information published or obtained since the proposed rule was published, including a study by Johnson *et al.* (in Press), additional survey data, and information received during the comment period.

The Suwannee moccasinshell (*Medionidus walkeri*) is a small freshwater mussel of the family Unionidae. The species was originally described by B.H. Wright in 1897. It was briefly considered a synonym of *Medionidus penicillatus* (Clench and

Turner 1956), but subsequently was recognized as a valid species by Johnson (1977, pp. 176–177), who described *walkeri* as being ''quite distinct'' from the other members of the genus. Its sharp posterior ridge and generally dark, rayless shell distinguishes it from other species of *Medionidus* in Gulf drainages (Johnson 1977, p. 177; Williams and Butler 1994, p. 86). Its distinctiveness as a separate species is recognized by recent authors (Williams and Butler 1994, pp. 85–86; Williams *et al.* 2014, pp. 278–280; Johnson *et al.* in Press).

The Suwannee moccasinshell typically inhabits larger streams where it is found in substrates composed of muddy sand or sand with some gravel, and in areas with slow to moderate current (Williams and Butler 1994, p. 86; Williams 2015, p. 2). The species is also associated with large woody material, and individuals are often found near embedded logs. Like other freshwater mussels, the Suwannee moccasinshell requires a fish host to complete its life cycle. Reproduction in freshwater mussels is unique in that they require specific fish species to serve as hosts for their larvae (called glochidia); the larval mussel must attach to the gills or fins of a suitable host fish in order to transform into a juvenile mussel. Parasitism serves as a means of upstream dispersal for this relatively sedentary group of organisms (Haag 2012, p. 145). A recent study examining the early life history of the Suwannee moccasinshell has provided information about its reproductive biology. Females were found gravid with mature glochidia from October to May (Johnson *et al.* in Press). In laboratory trials, Suwannee moccasinshell glochidia transformed only on darters—primarily on the blackbanded darter (*Percina nigrofasciata*) and to a lesser extent on the brown darter (*Etheostoma edwini*)—indicating that the mussel is a host specialist and dependent on darters for reproduction (Johnson *et al.* in Press). Darters are small, bottom-dwelling fish that generally do not move considerable distances (Freeman 1995, pp. 363–365; Holt 2013, p. 657). Thus, the exclusive use of darters as a host may limit the Suwannee moccasinshell's ability to disperse and to recolonize some areas from which it has become extirpated.

The Suwannee moccasinshell is endemic to the Suwannee River Basin in Florida and Georgia. Its historical range includes the lower and middle Suwannee River mainstem, and two large tributary rivers—the Santa Fe River subbasin and the lower Withlacoochee River mainstem (Williams 2015, p. 7). An evaluation of historical and recent collection data show that its range has declined in recent decades, and the species is presently known only from the middle Suwannee River and lower Santa Fe River in Florida. In the Suwannee River mainstem, the species occurs intermittently throughout a 75-mile (121-kilometer) reach of the middle river, and sporadically in a 28-mile (45-kilometer) segment of the lower Santa Fe River. The species was not detected in recent surveys in the Withlacoochee River or in the upper Santa Fe River subbasin. A summary of Suwannee moccasinshell occurrence and distribution by waterbody are shown in Table 1 below.

In addition to a reduction of range, recent surveys targeting the Suwannee moccasinshell show that its numbers are very low. Florida FWC and Georgia Department of Natural Resources biologists surveyed 144 sites during 2013–2015, covering nearly all of its historical range (FFWCC 2015 unpub. data; USFWS 2015 unpub. data). Suwannee moccasinshell densities were found to be exceedingly low in comparison to other mussel species, particularly in the lower Santa Fe River. A summary of survey results are shown in Table 2 below.

TABLE 1—SUMMARY OF SUWANNEE MOCCASINSHELL POPULATIONS BY WATERBODY

Water body	State and county	Occurrence *	Distribution and abundance
Suwannee River mainstem	FL: Madison Suwannee, Lafayette, Gilchrist, Dixie, Levy.	Recent	Occurs in a 75-mile reach of middle river; abundance low but population stable. May be extirpated from the lower river.
Lower Santa Fe River	FL: Suwannee, Gilchrist, Columbia, Alachua, Union, Bradford.	Recent	Occurs in 28-mile reach in lower river; drastic decline and abundance very low.
Upper Santa Fe and New Rivers	FL: Union, Alachua, Bradford	Historical	May be extirpated; last collected in system in 1996.
Withlacoochee River	GA: Brooks, Lowndes; FL: Madison, Hamilton	Historical	May be extirpated; last collected in system in 1969.

* Recent occurrence is based on collections made from 2000 to 2015; historical occurrence is based on collections made prior to 2000.

TABLE 2—SUMMARY OF 2013–2015 SUWANNEE MOCCASINSHELL SURVEYS BY WATERBODY

Water body	Survey year	Number of sites	Total mussels	Live suwannee moccasinshells
Suwannee River mainstem	2013–2015	103	15,195	73
Lower Santa Fe River	2015	15	7,044	1
Upper Santa Fe and New Rivers	2015	19	1,969	0
Withlacoochee River	2014–2015	17	4,377	0

Historical mussel collection data are often limited, making it difficult to compare trends in abundance over time. However, it does seem clear from museum collections that Suwannee moccasinshell numbers have declined over time, especially in the Santa Fe River subbasin where it has declined dramatically in recent decades (see our discussion on page 60339 of the proposed rule (80 FR 60335, October 6, 2015). Despite its low abundance, populations in the Suwannee River mainstem presently appear to be stable. We attribute its persistence in the mainstem to the stability of habitat and the attenuation of certain threats by larger flow volumes (threats are summarized below).

Summary of Threats

Below we present a summary of the threats information discussed in the proposed listing rule. We also present new information published or obtained since the proposed rule was published

and information received during the comment period.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The stream habitats of freshwater mussels are vulnerable to degradation and modification from a number of threats associated with modern civilization. Within the Suwannee River Basin, a rapidly growing human population and changing land use represent significant threats to the aquatic ecosystem, primarily through pollution and water withdrawal (Katz and Raabe 2005, p. 14). The Suwannee moccasinshell's habitat is subject to degradation as a result of pollutants discharged from industries, mines, and sewage treatment facilities, polluted runoff from agricultural lands, reduced flows as a result of groundwater extraction and drought, and stream channels destabilized by scouring floods and other perturbations.

Two pollutants of particular concern to the Suwannee moccasinshell are ammonia and pesticides. Both are highly toxic to freshwater mussels, particularly juveniles, and both are widely used on agricultural lands within the basin. Ammonia is also a common pollutant in wastewater discharged into streams of the basin by numerous permitted wastewater treatment facilities. Another concern is that nitrogen and phosphorus levels have increased within the range of the Suwannee moccasinshell. In excess, these two plant nutrients may indirectly affect the species by causing algal blooms that deplete oxygen and cause dense mats of filamentous algae that entrain juveniles.

Perhaps the most significant threat to Suwannee moccasinshell populations is flow reduction due to the withdrawal of groundwater. Groundwater pumping for agricultural purposes in neighboring basins, along with periods of extreme drought conditions, has caused unprecedented declines in groundwater levels, resulting in decreases in the amount of groundwater entering streams of the basin. Flow declines of approximately 30 percent have been observed in the lower Santa Fe and lower Suwannee Rivers; the upper Santa Fe River, once a perennial system, has gone dry multiple times since 2000 (Johnson *et al.* in Press). Reduced flows may exacerbate drought conditions (elevating temperature, pH, and pollutant concentrations (causing biotic die-off, and reducing dissolved oxygen), which in turn may have lethal or other harmful effects (prematurely aborting glochidia, reduced growth rates) to the species, or may cause stranding mortality.

Stream Channel Instability

In the following paragraphs, we include a full discussion of stream channel instability, a threat identified by a peer reviewer and not discussed in the proposed rule.

The Suwannee moccasinshell requires geomorphically stable stream channels to maintain its habitats. Channel instability occurs when the natural erosion process is accelerated, leading to erosion (degradation) and sediment deposition (aggradation). Channel instability can cause profound changes to mussel habitats due to scouring and sediment deposition (Hartfield 1993, p. 138). Channels can become destabilized as a result of physical alterations to the stream channel (such as dredging, straightening, impounding, and hardening), and because of alterations to the flow regime. Changes to land use that accelerate surface runoff (for example, croplands and development) can increase the amount and rate in which stormwater runoff enters stream channels, causing increases in flow volume and velocity. These more forceful flows can scour the streambed and banks and eventually lead to channel incision (lowering of the streambed) (Booth 1990, p. 407; Wood and Armitage 1997, pp. 204–205; Doyle *et al.* 2000, pp. 156–157, 175). Disturbance to riparian areas (particularly the removal of vegetation) can also lead to bank erosion (Rosgen 1996, pp. 8–11). This accelerated erosion process can also cause sedimentation in downstream areas (Waters 1995, pp. 44–47, 172; Rosgen 1996, pp. 6–31, 8–32–33; Doyle *et al.* 2000, p. 156). Sampling conducted in 2015 by FWC biologists in a reach of the Santa Fe River in Alachua County revealed the river has highly eroded banks and an incised channel with much unconsolidated sand substrates (FFWCC 2015 unpub. data). Increased stormwater runoff from a nearby town and surrounding agricultural lands are likely responsible for these changes in channel geomorphology (M. Rowe, *in litt.*).

Other sources of physical disturbance to mussel habitat include motorboat wakes frequently striking shores and the removal of large woody material. Boat wakes have been shown to cause significant bank erosion and sediment resuspension in river systems (Bauer *et al.* 2002, pp. 156–161). This problem appears to be especially severe in the lower Santa Fe River, which is a relatively narrow channel and is frequented by large numbers of motorboats (M. Rowe, *in litt.*). The removal of large woody material, especially wood embedded in the substrate, can cause the destabilization of microhabitat occupied by the Suwannee moccasinshell. Suwannee moccasinshell individuals are often found near embedded logs, which may stabilize the habitat and provide refuge for its host fishes. Over 7,200 pre-cut submerged (deadhead) logs have been removed from the Suwannee River, more than any other river in Florida (FDEP 2014 unpub. data). The removal of deadhead logs and snags can compromise habitat stability and affect channel morphology (Watters 1999, p. 269; Linohss *et al.* 2012, p. 160).

Many of the threats discussed above are greater in the two tributary systems, as evidenced by the species' possible disappearance from the Withlacoochee River and upper Santa Fe River subbasins. Currently, nearly the entire population resides in the middle reach of the Suwannee River mainstem. In the mainstem, flows are generally sustained, and pollutant concentrations may be diluted by larger flow volumes. In addition, geomorphically stable limestone and reduced surface runoff contribute to habitat stability in the mainstem Suwannee River.

While there are programs in place that may indirectly alleviate some detrimental impacts on aquatic habitats, there currently are no conservation efforts designed specifically to protect or recover Suwannee moccasinshell populations. Therefore, we conclude that habitat degradation is presently a significant threat to Suwannee moccasinshell populations in the Withlacoochee and Santa Fe River subbasins, and a moderate threat to populations in the Suwannee River main channel. This threat is expected to continue into the future and, because it is linked to human activities, is expected to increase as the human population within the Suwannee River Basin grows.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The Suwannee moccasinshell is not a commercially valuable species, and collecting is not considered a factor in its decline. Therefore, we do not consider overutilization to be a threat to the Suwannee moccasinshell at this time.

Factor C. Disease or Predation

We have no specific information indicating that disease or predation is negatively impacting Suwannee moccasinshell populations. Therefore,

we do not consider these to be threats to the Suwannee moccasinshell at this time.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Despite existing authorities such as the Clean Water Act, pollutants continue to impair water quality throughout the range of the Suwannee moccasinshell. State and Federal regulatory mechanisms have helped reduce the negative effects of point source discharges since the 1970s, yet these regulations are difficult to implement and regulate, and may not provide adequate protection for sensitive aquatic organisms like freshwater mussels. While new water quality criteria are being developed that take into account more sensitive aquatic species, most criteria currently do not. Thus, we conclude that existing regulatory mechanisms do not adequately protect the Suwannee moccasinshell.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Several other natural and manmade factors are negatively impacting the Suwannee moccasinshell. The Gulf coastal region is prone to extreme hydrologic events including droughts and flooding. Extended droughts (along with groundwater extraction) can cause severely reduced flows, exposing mussels to higher water temperatures, lower dissolved oxygen levels, and predators. Heavy rainfall events can cause scouring floods that dislodge mussels and alter stream channels, especially in smaller streams. Although floods and droughts are a natural part of the hydrologic processes that occur in river systems, these events may exacerbate the decline of mussel populations suffering the effects of other threats.

Accidental contaminant releases from industrial and municipal facilities and mining operations are a constant threat to the Suwannee moccasinshell as numerous potential sources are present throughout the basin, and these spills have occurred in the past. Spills as a result of transportation accidents are a potential threat as numerous railroads and highways traverse the basin. Because of the linear nature of the Suwannee moccasinshell's habitat and its reduced range, a major contaminant spill has the potential to impact a large portion of the population.

The introduced Asian clam (*Corbicula fluminea*) is widespread in the Suwannee River Basin, and can be found in high densities within the range of the Suwannee moccasinshell. Although the specific interaction between the Asian clam and native mussels is not well understood, enough information exists to conclude that dense Asian clam populations would negatively affect native mussels.

Numerous impacts associated with changing climatic patterns may amplify stressors currently impacting the Suwannee moccasinshell, including the prospect of more frequent and intense droughts and increased temperatures. These changes would further exacerbate current problems associated with reduced flows and degraded water quality. Saltwater encroachment also has the potential to impact moccasinshell populations in the lower river, especially during low flow conditions. The variables related to climate change are complex, and it is difficult to predict all of the possible ways climate change will affect Suwannee moccasinshell populations. However, information available is sufficient to indicate that climate change is a significant threat in the future, as it will likely exacerbate certain stressors already affecting the species.

Finally, the Suwannee moccasinshell's small population size and restricted range make it more vulnerable to threats associated with habitat degradation and catastrophic events. Therefore, we find that other natural or manmade factors, as a whole, pose a significant threat to the Suwannee moccasinshell, both now and continuing into the future.

Determination

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Suwannee moccasinshell. The primary reason for the Suwannee moccasinshell's decline is the degradation of its habitat due to polluted runoff from agricultural lands, polluted discharges from industrial and municipal facilities and mining operations, decreased flows due to groundwater extraction and drought, and stream channel instability (Factor A). These threats occur throughout its range, but are more intense in the two tributaries, the Withlacoochee and Santa Fe River systems. In portions of its range, sedimentation has also impacted its habitat.

Other threats to the species include State and Federal water quality standards that are inadequate to protect sensitive aquatic organisms like mussels (Factor D); accidental contaminant releases from industrial, municipal, and mining sources, and as a result of transportation accidents (Factor E); increased drought frequency and higher temperatures as a result of changing climatic conditions (Factor E); greater vulnerability to certain threats because of small population size and range (Factor E); and competition and disturbance from the introduced Asian clam (Factor E). These threats have resulted in the decline of the species throughout its range, and pose the highest risk to populations in the two tributary systems, as evidenced by the species' decline and possible disappearance in the Withlacoochee River, and its decline in the Santa Fe River subbasin. In addition, the species likely has a limited ability to disperse and, therefore, may not be able recolonize areas from which it has been extirpated.

Currently, nearly the entire population resides in the middle and lower reach of the Suwannee River main channel, where the two greatest threats, pollutants and reduced flows, are attenuated by higher flow volumes. Therefore, Suwannee moccasinshell populations in the Withlacoochee and Santa Fe River subbasins are presently facing threats that are high in magnitude, and populations in the Suwannee River main channel are presently facing threats that are moderate in magnitude. Most of these threats, including reduced flows, pollution, degraded water quality, and channel instability, are expected to increase in the future due to human population growth and climate change.

The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' We find that the Suwannee moccasinshell presently is likely to

become endangered throughout all or a significant portion of its range within the foreseeable future based on the severity and immediacy of threats currently impacting the species. The Suwannee moccasinshell's range and abundance have been reduced, and its remaining habitat and populations are threatened by a variety of factors acting in combination to reduce the overall viability of the species. The risk of becoming endangered is high because remaining populations are small, linearly distributed within the mainstem Suwannee River, and numerous threats can impact those populations.

Under the Act and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. Because we have determined that the Suwannee moccasinshell is threatened throughout all of its range, no portion of its range can be ''significant'' for purposes of the definitions of ''endangered species'' and ''threatened species.'' See the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37577, July 1, 2014).

Therefore, on the basis of the best available scientific and commercial information, we are listing the Suwannee moccasinshell as threatened in accordance with sections 3(6) and 4(a)(1) of the Act. We find that endangered species status is not appropriate, because despite low population densities and numerous threats, the populations in the mainstem presently appear to be stable, which has been attributed to the threats being attenuated and the streambed habitat being stable.

Critical Habitat

Section 3(5)(A) of the Act defines critical habitat as: (i) The specific areas within the geographical area occupied by the species, at the time it is listed on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed upon a determination by the Secretary that such areas are essential for the conservation of the species.

Section 4(a)(3) of the Act and implementing regulations (50 CFR 424.12) require that we designate critical habitat at the time a species is determined to be an endangered or threatened species, to the maximum extent prudent and determinable. Our regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist: (1) The species is threatened by taking or other activity and the identification of critical habitat can be expected to increase the degree of threat to the species; or (2) such designation of critical habitat would not be beneficial to the species. As discussed above (see *Factor B* discussion), there is currently no imminent threat of take or other overutilization for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In the absence of finding that the designation of critical habitat would increase threats to a species, if there are any benefits to a critical habitat designation, a finding that designation is prudent is warranted. Here, the potential benefits of designation include: (1) Triggering consultation under section 7 of the Act, in new areas for action in which there may be a Federal nexus where it would not otherwise occur because, for example, it is unoccupied; (2) focusing conservation activities on the most essential features and areas; (3) providing educational benefits to State or county governments or private entities; and (4) preventing inadvertent harm to the species. Accordingly, because we have determined that the designation of critical habitat will not likely increase the degree of threat to the species and may provide some measure of benefit, we determine that designation of critical habitat is prudent for the Suwannee moccasinshell.

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the species is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist: (i) Information sufficient to perform required analyses of the impacts of the designation is lacking, or (ii) the biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

As discussed above, we have reviewed the available information pertaining to the biological needs of the species and habitat characteristics where this species is located. On the basis of a review of available information, we find that critical habitat for the Suwannee moccasinshell is not determinable because the specific information sufficient to perform the required analysis of the impacts of the designation is currently lacking, such as information on areas to be proposed for designation and the potential economic impacts associated with designation of these areas. We are in the process of obtaining this information, and we intend to publish a proposed rule in the **Federal Register** to designate critical habitat for the Suwannee moccasinshell in the near future.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act requires the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan identifies site-specific management actions that set a trigger for review of the five factors that control whether a species remains endangered or may be downlisted or delisted, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate

their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our Web site (*http://www.fws.gov/endangered*) or from our Panama City Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribal, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive-propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

Following publication of this final listing rule, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Florida and Georgia will be eligible for Federal funds to implement management actions that promote the protection or recovery of the Suwannee moccasinshell. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Please let us know if you are interested in participating in recovery efforts for the Suwannee moccasinshell. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require consultation as described in the preceding paragraph include issuance of section 404 Clean Water Act permits by the U.S. Army Corps of Engineers; construction and maintenance of roads, highways, or bridges by the U.S. Department of Transportation's Federal Highway Administration; funding of various projects administered by the U.S. Department of Agriculture's Natural Resources Conservation Service and the Federal Emergency Management Agency; and management and any other landscape-altering activities on Federal lands administered by the U.S. Fish and Wildlife Service or the U.S. Forest Service.

Under section 4(d) of the Act, the Service has discretion to issue regulations that we find necessary and advisable to provide for the conservation of threatened species. The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to threatened wildlife. The prohibitions of section 9(a)(1) of the Act, as applied to threatened wildlife through regulations codified at 50 CFR 17.31, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) threatened wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any listed species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a final listing on proposed and ongoing activities within the range of a listed species. Based on the best available information, the following actions may result in a violation of section 9 of the Act; this list is not comprehensive:

(1) Unauthorized handling or collecting of the species;

(2) Destruction or alteration of the species' habitat by discharge of fill material, dredging, snagging, impounding, channelization, or modification of stream channels or banks;

(3) Discharge of pollutants into a stream or into areas hydrologically connected to a stream occupied by the species; and

(4) Diversion or alteration of surface or ground water flow.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Panama City Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Required Determinations

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of

the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes. The Suwannee moccasinshell is not known to occur within any tribal lands or waters.

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* and upon request from the Panama City Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this final rule are the staff members of the Panama City Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245; unless otherwise noted.

■ 2. Amend § 17.11(h) by adding an entry for ''Moccasinshell, Suwannee'' to the List of Endangered and Threatened Wildlife in alphabetical order under CLAMS to read as set forth below:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
CLAMS				
*	*	*	*	*
Moccasinshell, Suwannee.	*Medionidus walkeri*	Wherever found	T	81 FR [Insert **Federal Register** page where the document begins]; October 6, 2016.
*	*	*	*	*

Dated: September 26, 2016.

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2016–24138 Filed 10–5–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[4500090022]

Endangered and Threatened Wildlife and Plants; 12-Month Findings on Petitions To List 10 Species as Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12-month petition findings.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce 12-month findings on petitions to list 10 species as endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). After a review of the best available scientific and commercial information, we find that listing the Huachuca-Canelo population of the Arizona treefrog, the Arkansas darter, black mudalia, Highlands tiger beetle, *Dichanthelium (=panicum) hirstii* (Hirst Brothers' panic grass), two Kentucky cave beetles (Louisville cave beetle and Tatum Cave beetle), relict leopard frog, sicklefin redhorse sucker, and Stephan's riffle beetle is not warranted at this time. However, we ask the public to submit to us at any time any new information that becomes available concerning the stressors to any of the 10 species listed above or their habitats.

DATES: The findings announced in this document were made on October 6, 2016.

ADDRESSES: Detailed descriptions of the basis for each of these findings are available on the Internet at *http://www.regulations.gov* at the following docket numbers:

Species	Docket No.
Arizona treefrog (Huachuca-Canelo population)	FWS–R2–ES–2016–0111.
Arkansas darter	FWS–R6–ES–2016–0113.
Black mudalia	FWS–R4–ES–2016–0112.
Highlands tiger beetle	FWS–R4–ES–2016–0114.
Dichanthelium (=panicum) hirstii (Hirst Brothers' panic grass)	FWS–R5–ES–2016–0105.
Kentucky cave beetles (Louisville cave beetle and Tatum Cave beetle)	FWS–R4–ES–2016–0115.
Relict leopard frog	FWS–R8–ES–2016–0116.
Sicklefin redhorse sucker	FWS–R4–ES–2016–0117.
Stephan's riffle beetle	FWS–R2 ES–2016–0118.

Supporting information used to prepare these findings is available for public inspection, by appointment, during normal business hours, by contacting the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**. Please submit any new information, materials, comments, or questions concerning these findings to the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

Species	Contact information
Arizona treefrog (Huachuca-Canelo population)	Nathan Allan, Acting Listing Coordinator, Southwest Regional Office, Ecological Services, 512–490–0057.
Arkansas darter	Jason Luginbill, Field Supervisor, Kansas Ecological Services Field Office, 785–539–3474.
Black mudalia	Bill Pearson, Field Supervisor, Alabama Ecological Services Field Office, 251–441–5181.
Highlands tiger beetle	Roxanna Hinzman, Field Supervisor, South Florida Ecological Services Field Office, 772–562–3909.
Dichanthelium (=panicum) hirstii (Hirst Brothers' panic grass).	Krishna Gifford, Listing Coordinator, Northeast Regional Office, Ecological Services, 413–253–8619. Submit any new information concerning the species' taxonomy, population status, or threats to: New Jersey Ecological Services Field Office, 4 E. Jimmie Leeds Road, Suite 4, Galloway, NJ 08205.
Kentucky cave beetles (Louisville cave beetle and Tatum Cave beetle).	Lee Andrews, Field Supervisor, Kentucky Ecological Services Field Office, 502–695–0468.
Relict leopard frog	Michael Senn, Field Supervisor, Southern Nevada Ecological Services Field Office, 702–515–5244.
Sicklefin redhorse sucker	Jason Mays, Asheville (North Carolina) Ecological Services Field Office, 828–258–3939.
Stephan's riffle beetle	Steve Spangle, Field Supervisor, Arizona Ecological Services Field Office, 602–242–0210.

If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Act (16 U.S.C. 1533) requires that, within 12 months after receiving any petition to revise the Federal Lists of Endangered and Threatened Wildlife and Plants that contains substantial scientific or commercial information indicating that listing an animal or plant species may be warranted, we make a finding (''12-month finding''). In this finding, we determine whether listing the Huachuca-Canelo population of the Arizona treefrog, the Arkansas darter, black mudalia, Highlands tiger beetle, *Dichanthelium (=panicum) hirstii* (Hirst Brothers' panic grass), two Kentucky cave beetles (Louisville cave beetle and Tatum Cave beetle), relict leopard frog, sicklefin redhorse sucker, and Stephan's riffle beetle is: (1) Not warranted; (2) warranted; or (3) warranted, but the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are endangered or threatened species, and expeditious progress is being made to add or remove qualified species from the Federal Lists of Endangered and Threatened Wildlife and Plants (''warranted but precluded''). Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. We must publish these 12-month findings in the **Federal Register**.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. The Act defines ''endangered species'' as any species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and ''threatened species'' as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, a species may be determined to be an endangered or a threatened species because of any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

We summarize below the information on which we based our evaluation of the five factors provided in section 4(a)(1) of the Act to determine whether the Huachuca-Canelo population of the Arizona treefrog, the Arkansas darter, black mudalia, Highlands tiger beetle, *Dichanthelium (=panicum) hirstii,* two Kentucky cave beetles (Louisville cave beetle and Tatum Cave beetle), relict leopard frog, sicklefin redhorse sucker, and Stephan's riffle beetle meet the definition of an endangered or threatened species. More detailed information about these species is presented in the species-specific assessment forms found on *http://www.regulations.gov* under the appropriate docket number (see **ADDRESSES**, above).

In considering what stressors under the Act's five factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat. In that case, we determine if that stressor rises to the level of a threat, meaning that it may drive or contribute to the risk of extinction of the species such that the species warrants listing as an endangered or threatened species as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely affected could suffice. The mere identification of stressors that could affect a species negatively is not sufficient to compel a finding that

listing is appropriate; we require evidence that these stressors are operative threats to the species and its habitat, either singly or in combination, to the point that the species meets the definition of an endangered or a threatened species under the Act.

In making our 12-month findings, we considered and evaluated the best available scientific and commercial information regarding the past, present, and future stressors and threats. We reviewed the petition, information available in our files, and other available published and unpublished information. This evaluation may include information from recognized experts; Federal, State, and tribal governments; academic institutions; foreign governments; private entities, and other members of the public.

Arizona Treefrog, Huachuca-Canelo Population (*Hyla wrightorum*)

Previous Federal Actions

In our annual candidate notice of review (CNOR) published on December 6, 2007 (72 FR 69034), we recognized the Huachuca-Canelo population of the Arizona treefrog as a candidate for listing as a distinct population segment (DPS). Subsequently, we published similar findings in our CNORs on December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), November 10, 2010 (75 FR 69222), October 26, 2011 (76 FR 66370), November 21, 2012 (77 FR 69994), November 22, 2013 (78 FR 70104), December 5, 2014 (79 FR 72450), and December 24, 2015 (80 FR 80584). In 2007, the Huachuca-Canelo population of the Arizona treefrog was assigned a listing priority number (LPN) of 3, reflecting the taxonomic identity of the listable entity as a subspecies/population with threats that we considered to be imminent and high in magnitude. The LPN numbers range from 1 to 11, with 1 being the highest priority.

Background

The Arizona treefrog (*Hyla wrightorum*) is a small (4.6 centimeters (cm) (1.8 inches (in)) green frog with a dark eyestripe that extends past the shoulder onto the side of the body, and sometimes to the groin area. It occurs in Madrean oak woodland and savannah, pine-oak woodland, mixed conifer forest, and Plains grasslands at elevations of approximately 1,525 to 2,590 meters (m) (5,000 to 8,500 feet (ft)), and requires ponds for successful reproduction.

The Arizona treefrog is known to occur within Arizona, New Mexico, and Mexico. In Arizona and New Mexico, the Arizona treefrog occurs along the Mogollon Rim (central Arizona and western New Mexico), in the Huachuca Mountains and Canelo Hills area (a disjunct mountain range on the Arizona/Sonora, Mexico border), and farther south in Mexico (in the Sierra Madre Occidental and sky island mountain ranges). We refer to these three areas as the Mogollon Rim, Huachuca-Canelo, and Mexico populations.

Within the Huachuca-Canelo population, historical information has documented Arizona treefrogs from three general localities at Rancho Los Fresnos, Sonora, Mexico, and from 13 to 15 verified localities in the Huachuca Mountains and Canelo Hills, Arizona. The Huachuca-Canelo population of Arizona treefrog has continued to persist in Arizona sky island mountain range and Plains grassland habitats, and the treefrog has recently been found in new locations within grasslands and ciénegas (a swamp or marsh, especially one formed and fed by springs) in Arizona. These new locations in varied habitats indicate that the Arizona treefrogs may be less selective in choosing breeding habitat than previously thought. In addition, the species likely occurs in other wet canyons with suitable breeding habitat in the Huachuca Mountains, and perhaps in ciénegas in the vicinity of Rancho Los Fresnos.

The Huachuca-Canelo DPS of the Arizona treefrog was originally defined based on the historical locations. However, recently the Service has received information on Arizona treefrog locations nearby, but outside of, the DPS area. This new information, along with many new location detections in the Huachuca Mountains and Canelo Hills, indicates that the Arizona treefrog is not only more numerous, but is much more widespread than we knew when the Service made this Arizona treefrog a candidate species as a DPS. There are now approximately more than 30 known localities in Arizona in the Huachuca Mountains and Canelo Hills, and the Arizona treefrog also occurs in areas outside of the DPS boundary, but within the vicinity of the Huachuca Mountains and Canelo Hills.

Summary of Status Review

Based on new information and review of previously referenced studies, we find that the Huachuca-Canelo population of the Arizona treefrog does not meet the requirements of the Service's Policy Regarding the Recognition of Distinct Vertebrate Population Segments (DPS Policy) published in the **Federal Register** on February 7, 1996 (61 FR 4722). The DPS Policy sets forth three elements for the Service to consider in determining whether a vertebrate population is a DPS that warrants listing: Whether the population is discrete and whether the population is significant. If the population is determined to be both discrete and significant, then the DPS Policy requires the Service to evaluate the conservation status of the population to determine whether the population falls within the Act's definition of an ''endangered species'' or of a ''threatened species.''

On the basis of the best available scientific and commercial information, and in accordance with our DPS Policy, we conclude that the Huachuca-Canelo population of the Arizona treefrog is discrete but it is not significant (*i.e.,* it is not biologically or ecologically important) to the taxon as a whole. Regarding discreteness, we have reviewed the best available scientific and commercial information and the evidence relative to potential differences in physical, behavioral, morphological, and genetic attributes. We conclude that the Huachuca-Canelo population of the Arizona treefrog is discrete based on its geographical separation from the other two populations on the Mogollon Rim and in Mexico.

Regarding significance, we considered the four classes of information listed in the DPS Policy as possible considerations in making a determination, as well as all other information that might be relevant to making this determination for the Huachuca-Canelo population. The Huachuca-Canelo population of the Arizona treefrog does not appear to exhibit any direct or indirect habitat adaptation or behavioral advantage that would indicate that their persistence in the Huachuca Mountains and Canelo Hills area is biologically or ecologically important to the taxon as a whole. Moreover, we considered the other three considerations that the DPS Policy sets out for evaluating significance, and none of them provides evidence that the Huachuca-Canelo population is significant to the Arizona treefrog as a whole: (1) Loss of the Huachuca-Canelo population would not result in a significant gap in the range; (2) the Huachuca-Canelo population does not represent the only surviving natural occurrence of the Arizona treefrog; and (3) the Huachuca-Canelo population's genetic characteristics do not differ markedly from those of other Arizona treefrog populations.

Finding

Based on our review of the best available scientific and commercial information pertaining to the Act's five threat factors, we conclude that the Huachuca-Canelo population of the Arizona treefrog does not meet the significance criterion of the DPS Policy, as detailed above and, therefore, is not a valid DPS under our DPS Policy. As a result, we find that the Huachuca-Canelo population of the Arizona treefrog is not a listable entity under section 3(16) of the Act. Therefore, we find that listing the Huachuca-Canelo population of Arizona treefrog as an endangered or a threatened species is not warranted throughout all or a significant portion of its range at this time, and consequently, we are removing it from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Huachuca-Canelo population of the Arizona treefrog. A detailed discussion of the basis for this finding can be found in the species-specific assessment form for the Huachuca-Canelo population of the Arizona treefrog and other supporting documents (see **ADDRESSES**, above).

Arkansas Darter (*Etheostoma cragini*)

Previous Federal Actions

The Arkansas darter was first identified as a candidate for listing under the Act in 1989 (54 FR 554; January 6, 1989), as a Category 2 candidate species. Category 2 candidate species were identified as those taxa for which the Service possessed information indicating proposing to list the taxa was possibly appropriate, but for which conclusive data on biological vulnerability and threats sufficient to support a proposed listing rule was lacking. On February 28, 1996, the CNOR (61 FR 7596) discontinued recognition of Categories 1–3. Because listing the Arkansas darter was warranted but precluded, we assigned the species an LPN of 5. In 2002, we changed the LPN from 5 to 11 (67 FR 40657; June 13, 2002).

On May 11, 2004, the Service received a petition dated May 4, 2004, from the Center for Biological Diversity and others to list 225 species, including the Arkansas darter. The Service published a 12-month finding in the **Federal Register** on May 11, 2005, with a reaffirmed determination that listing was warranted but precluded and that the taxon had an LPN of 11 (70 FR 24870). We have continued to evaluate the status of the candidate taxon through our annual CNOR and maintained the LPN of 11 for this species (see September 12, 2006 (71 FR 53756), December 6, 2007 (72 FR 69034), December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), November 10, 2010 (75 FR 69222), October 26, 2011 (76 FR 66370), November 21, 2012 (77 FR 69994), November 22, 2013 (78 FR 70104), December 5, 2014 (79 FR 72450), and December 24, 2015 (80 FR 80584)).

Background

The Arkansas darter (*Etheostoma cragini*) is a small fish in the perch family native to the Arkansas River basin. The species occurs most often in sand- or pebble-bottomed pools of small, spring-fed streams and marshes, with cool water, and broad-leaved aquatic vegetation. Arkansas darters prefer flowing, spring-fed streams and pools in contact with groundwater sources. However, the species is very tolerant to periods of very poor water quality, including high water temperatures, low dissolved oxygen, high turbidity, and hyper-eutrophication.

The Arkansas darter's range includes eastern Colorado, southwest and central Kansas, northwest and northeast Oklahoma, southwest Missouri, and northwest Arkansas. Recent surveys have expanded our knowledge of occupied Arkansas darter populations. We currently consider to be extant a total of 80 populations within 15 metapopulations rangewide. This is more than we knew of for previous assessments of this species.

Summary of Status Review

In completing our status review for the Arkansas darter, we reviewed the best available scientific and commercial information and compiled this information in the Species Status Assessment Report (SSA Report) for the Arkansas darter. In previous candidate assessments and findings for this species, the identified threats we considered were water depletion, water quality degradation, urbanization and development, confined-animal feeding operations, dams and reservoirs, salt cedar invasion, disease, and predation. Although localized negative effects have been observed, all of these stressors (other than water depletion) occur at a limited scale and scope, and the overall impact at the population and species level is minimal.

Water depletion is the stressor with the largest potential impact to the Arkansas darter's viability, affecting approximately 25 percent of the geographic range, resulting mainly from groundwater withdrawals for agriculture. Seasonal low flows and intermittency of streams are common within the Great Plains portion of its range, and it appears the species is adapted to this phenomenon. However, the continued existence of the species in these areas is dependent on localized areas of refugia. Typically refugia exist where groundwater flows come to the surface and create permanent pools or small wetland areas along the stream course. When seasonal precipitation occurs and the streams become flowing systems, typically in the spring, the stream then provides habitat for spawning, rearing, and dispersal of young and adult individuals throughout the watershed. Climate change projections forecast minimal change in average annual precipitation in the Arkansas River basin and do not forecast reduced or diminished streamflow as a result of future changes in precipitation patterns. Therefore, we do not expect to see climate-change-driven decreased trends in precipitation and related stream flows.

Water depletion results in decreased resiliency of populations affected in the portions of the range in southwestern Kansas, northwestern Oklahoma, and parts of Colorado, approximately 25 percent of the range. However, the species has endured over 40 years of groundwater withdrawals in these areas, indicating continued resiliency of these populations. The large number of populations (80) spread across the multi-State range provides the Arkansas darter species with a high level of redundancy should a catastrophic event occur somewhere within its occupied range. Multiple populations and metapopulations currently occupying the unique ecological settings of the three unique physiogeographic areas, the same physiogeographic areas that this species was known to occupy historically, allow the species to maintain adaptive potential and the underlying genetic makeup to adapt to changing environmental conditions.

Over the next 30 years, under our expected scenario, we are likely to see

a continuation of similar levels of impact from the stressors affecting this species as we have in the past. We believe a continued rate of groundwater usage and continued rates of impact from other stressors over the next 30 years would not likely result in significant effects to the occupied range of the Arkansas darter. Although we expect little change on a rangewide basis, we could see some range contraction in the western Cimarron and upper Rattlesnake Creek basin in Kansas and Oklahoma due to water depletion, as well as small portions of the Colorado range. Additionally, we could see range contraction in the eastern portion of the range (Arkansas, Kansas, Missouri, and Oklahoma) due to development effects. However, we do not expect to see a reduction in redundancy of the species overall (*e.g.,* no the loss of entire populations).

Finding

Based on our review of the best available scientific and commercial information pertaining to the Act's five threat factors, we find that the stressors acting on the species and its habitat, either singly or in combination, are not of sufficient imminence, intensity, or magnitude to indicate that the Arkansas darter is currently in danger of extinction (an endangered species), or likely to become endangered within the foreseeable future (a threatened species). In conclusion, we find that this species no longer warrants listing throughout its range.

We evaluated the current range of the Arkansas darter to determine if there is any apparent geographic concentration of potential threats for the species. Groundwater withdrawals are currently impacting portions of the upper, central, and lower Arkansas River basins in Kansas, Oklahoma, and Colorado, an area representing approximately 25 percent of geographic range of the Arkansas darter. Additional stressors outside of this area are generally low level, localized impacts not affecting entire populations. The 25 percent of the range affected by groundwater withdrawal does not meet the biologically based definition of ''significant'' (*i.e.,* the loss of that portion clearly would not be expected to increase the vulnerability to extinction of the entire species). If that 25 percent of the range were lost, the species would still have approximately 75 percent of its geographic range in areas that are not expected to be subject to the negative effects of water depletion. Therefore, we determined that there are no significant portions of the species' range where the Arkansas darter meets the definition of an endangered or a threatened species and that the best available scientific and commercial information indicates this species is no longer in danger of extinction (endangered) or likely to become endangered within the foreseeable future (threatened) throughout all or a significant portion of its range.

Arkansas darter populations appear to be resilient to threats identified in previous status assessments; these threats are now believed to have fewer impacts on the Arkansas darter than previously understood; the species is expected to maintain a high level of redundancy and representation into the future; we know of more currently-occupied populations then we have in previous assessments; and while groundwater withdrawals affecting water depletion are expected to continue in approximately 25 percent of the range, we do not expect to see a reduction in redundancy of the species overall (*e.g.,* no loss of Arkansas darter populations). Therefore, we find that listing the Arkansas darter as an endangered or threatened species is not warranted at this time, and consequently we are removing it from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Arkansas darter, and constitutes the Service's 12-month finding on the May 4, 2004, petition to list the Arkansas darter as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the Arkansas darter's species-specific assessment form, SSA Report, and other supporting documents (see **ADDRESSES**, above).

Black Mudalia (*Elimia melanoides*)

Previous Federal Actions

The Service first identified black mudalia as a candidate for listing in the September 12, 2006, CNOR and assigned an LPN of 2 based on imminent, high-magnitude threats (71 FR 53756). In the December 6, 2007, CNOR, we concluded that the threats were at the time moderate in magnitude and changed the LPN to 8 (72 FR 69034). We retained the LPN of 8 in all subsequent CNORs (see December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), November 10, 2010 (75 FR 69222), October 26, 2011 (76 FR 66370), November 21, 2012 (77 FR 69994), November 22, 2013 (78 FR 70104), December 5, 2014 (79 FR 72450), and December 24, 2015 (80 FR 80584)).

On April 20, 2010, we received a petition from the Center for Biological Diversity requesting that the Service list 404 species, including black mudalia, as endangered or threatened. No new information regarding black mudalia was presented in the petition, and on September 27, 2011, we published a 90-day finding (76 FR 59836).

Background

The species formerly described as the black mudalia is a small species of aquatic snail growing to 13 millimeters (mm) (0.5 inches (in)) in length and belongs to the aquatic snail family of Pleuroceridae. The species formerly described as the black mudalia was found clinging to clean gravel, cobble, boulders, and/or logs in flowing water on shoals and riffles within five streams in the Locust Fork drainage in Jefferson and Blount Counties, Alabama.

Summary of Status Review

The following summary is based on our review of the best available scientific and commercial information. No new information was provided in the petition we received on April 20, 2010. The species was described from ''rivers in North Alabama'' by T.A. Conrad as *Anculosotus melanoides,* but he failed to provide a specific type of locality. For the second half of the 20th century, the black mudalia was considered to be extinct. However, in 2003, Dr. Russell Minton published a paper on the apparent rediscovery of the species, with a re-description of what he believed was Conrad's black mudalia. He designated an individual from the upper Black Warrior Basin as the neotype—a biological specimen that is selected as the type specimen when the holotype (a single specimen chosen for designation of a new species), lectotype (a specimen chosen from syntypes to designate types of species), or any syntypes (any one specimen of a series used to designate a species when the holotype has not been selected) have been lost or destroyed—and restricted the type locality to one site on the Little Warrior River in Blount County, Alabama; however, the neotype is currently unavailable for study.

Recently, the Service's Alabama Ecological Services Field Office learned that a specimen at the Museum of Comparative Zoology in Boston, Massachusetts, identified by T.A. Conrad as *A. melanoides* is not the same species that was described by Minton *et al.* (2003). Therefore, we cannot with any certainty determine the status of either the entity that Conrad (1834) first described as *A. melanoides,* or the entity that Minton *et al.* (2003) re-described as *E. melanoides.* Additional taxonomic review, led by the Smithsonian Institution, is underway as of early 2016. The results of this review will require additional efforts to define *Elimia* spp. boundaries, status, and distribution within the Black Warrior River Basin.

Finding

The Act only allows listing of ''species'' as defined under Section 3(16)—that is, recognized species, subspecies, or distinct population segments of vertebrates. Based on our review of the best available scientific and commercial information, and in light of the best available scientific information regarding taxonomic uncertainty described above, we conclude that the black mudalia is not currently a recognized ''species.'' We are therefore removing the black mudalia from candidate status pending further study.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the black mudalia, and constitutes the Service's 12-month finding on the April 20, 2010, petition to list the black mudalia as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the black mudalia's species-specific assessment form and other supporting documents (see **ADDRESSES**, above).

Highlands Tiger Beetle (*Cicindela highlandensis*)

Previous Federal Actions

The Highlands tiger beetle was first recognized as a candidate species on November 21, 1991 (56 FR 58804), when we assigned the species an LPN of 2. In the October 30, 2001, CNOR (66 FR 54808), we changed the LPN for the Highlands tiger beetle from 2 to 5, because the immediacy of threats to the species' scrub habitat had decreased with the acquisition of scrub habitat by the State of Florida and conservation groups. On May 11, 2004, the Service received a petition dated May 4, 2004, from the Center for Biological Diversity and others to list 225 species as endangered or threatened, including the Highlands tiger beetle. The species was maintained as a candidate with an LPN of 5 through the 2015 CNOR (see June 13, 2002 (67 FR 40657); May 4, 2004 (69 FR 24876); May 11, 2005 (70 FR 24870); September 12, 2006 (71 FR 53756), December 6, 2007 (72 FR 69034), December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), November 10, 2010 (75 FR 69222), October 26, 2011 (76 FR 66370), November 21, 2012 (77 FR 69994), November 22, 2013 (78 FR 70104), December 5, 2014 (79 FR 72450), and December 24, 2015 (80 FR 80584)).

Background

The Highlands tiger beetle is elongate with an oval shape and bulging eyes, and is one of the smallest (7.0–9.5 mm) (0.28–0.37 in) tiger beetles in the United States. As is typical of other tiger beetles, adult Highlands tiger beetles are active diurnal predators that use their keen vision to detect movement of small arthropods and run quickly to capture prey with their well-developed mandibles (jaws). Tiger beetle larvae have an elongate white grub-like body and a dark or metallic head with large mandibles. Larvae are sedentary sit-and-wait predators occurring in permanent burrows flush with the ground surface. When feeding, larvae position themselves at the burrow mouth and quickly strike at and seize small arthropods that pass within a few centimeters of the burrow mouth. Larvae prey on small arthropods, similar to adults.

The Highlands tiger beetle occurs primarily in open sandy patches of Florida scrub habitat on the Lake Wales Ridge in Highlands and Polk Counties. The Lake Wales Ridge is one of the largest and oldest Florida scrub ecosystems. The harsh environment on the Lake Wales Ridge is characterized by hot weather, nutrient-poor sandy soils, and (historically) frequent wildfires. The Highlands tiger beetle is often associated with evergreen scrub oaks, as well as high pineland with deciduous turkey oak (*Quercus laevis*) and longleaf pine (*Pinus palustris*). High-quality habitat for the species is primarily scrub or sandhill having natural or management-created interior patches with a high percent of open sand (greater than 50 percent) that is continuous or connected to adjacent open patches by lightly disturbed trails or paths. The known extant range of the Highlands tiger beetle exists in the core of the suitable (scrub) habitat in the central and south-central portion of the Lake Wales Ridge, approximately 90 km (56 mi) in length and about 10 km (6 mi) in width).

Summary of Status Review

The following summary is based on information contained in our files. The Highlands tiger beetle is narrowly distributed and restricted to areas of bare sand within scrub and sandhill on ancient sand dunes of the Lake Wales Ridge in Polk and Highlands Counties, Florida. Adult tiger beetles have been found in 56 of the total 71 sites surveyed at the core of the Lake Wales Ridge. In 2004–2005 surveys, a total of 1,574 adults were found at four sites. A total of 643 adults at 31 sites were found in 1996, 928 adults at 31 sites in 1995, and 742 adults at 21 sites in 1993. A visual reference count of 2,231 adults was found from 46 sites in 2014. This increase in index counts over time can be attributed to new survey sites and finding a large number of beetles at these sites. Estimates from the visual reference (index) counts are used to provide an estimate of the populations. Results from a limited removal study suggest that the actual population size at some survey sites can be as much as two to three times as high as the visual reference. In addition, surveys for Highland tiger beetles were not exhaustive, and there are additional potential suitable habitats. An estimate of beetle numbers likely present in these additional potential habitats added to the modified index count produces an estimated minimum total abundance of 10,438 adults in at least 16 populations. Based on these expanded surveys and the findings of additional large beetle populations at these sites, it is determined that the Highland tiger beetle is more abundant than previously documented, and its habitat is of much better quality than previously documented. Of the 15 sites with the largest populations, 7 sites show an increase in number of individuals. The number of occupied sites identified as high or good quality also increased from 13 in 2005, to 21 in 2014, and of the currently known sites nearly half of them (21 of 46) are of high or good quality.

We evaluated all known potential impacts to the Highlands tiger beetle, including the Act's five threat factors. While these impacts were previously believed to pose imminent or significant threats to the species, and some may have caused losses to individuals or habitat, the updated information we received regarding species' occurrence and population size has improved our understanding on how the stressors affect the status of species. In our current candidate assessment, we evaluated the best available scientific and commercial information, and concluded that the species is resilient to these stressors and that current impacts to the species are not as strong as previously believed. Approximately 43.4 percent of the existing potential suitable habitat for the species is protected conservation lands. While fragmentation of the Lake Wales Ridge scrub and sandhill habitats exists, 63 percent of the Highlands tiger beetle populations occur on these protected conservation lands, including three of the largest known populations. These lands are managed for the scrub habitat and species, including the Highlands tiger beetle, through government and private partnership prescribed burn programs, invasive species control, best management practices, and enforcement and protection of the resources. Fragmentation of the habitat was identified as a stressor compromising the dispersal capabilities of Highlands tiger beetle populations. However, the new information on the number and distribution of occupied sites and population size indicates that the threat to the dispersal capabilities of the species is not as high as previously reported. New sites have been identified in four populations across the north to south range of the species, and the Lake Wales Ridge as a whole has areas of open lands, remnant scrub and sandhill, and patchworks of scrub roadside habitat that can act as corridors or ''stepping stones'' for Highlands tiger beetle movement and flight, making active migration to new sites or the exchange of individuals between sites feasible for this species. In addition, storm winds, water flow, rafting transport, and animals are possible means of stochastic dispersal of individual beetles.

As a result of the new information and analysis, we no longer consider the threats originally identified in our previous 12-month finding for the Highlands tiger beetle to be current or foreseeable threats for the following reasons: (1) The species is larger in individual numbers and occurs in more sites across its range than previously documented; (2) the populations occur primarily on protected conservation lands; (3) more than half of the potential suitable habitat for the species consists of protected lands under conservation management, with new conservation lands and conservation banks acquired in 2014; (4) the species occurs in 16 populations across 225,920 acres (91,426 hectares) or 353 square miles (920 square kilometers), and existing unsurveyed suitable habitat occurs in the species' range; (5) new survey information has identified an increased number of sites graded as ''high'' and ''good'' quality habitat for the Highlands tiger beetle; (6) the analysis reveals annual prescribed burning schedules are being implemented across the range of the Highlands tiger beetle on government and private conservation lands; and (7) the stressors identified in the 2015 candidate assessment, including collections, occur at the individual level but are not rising to the level of population or species impacts.

Overall, current information from additional surveys indicates an increase in occupied sites with a large increase in the number of beetles. Most threats are being addressed through the presence of large populations of the species occurring on protected lands and through the management actions that occur on these lands. Any actual impact from threats occurs at the individual, not population or species, level, and no impact, individually or cumulatively, rises to the level that it contributes to making the species meet the definition of ''threatened species'' or ''endangered species.''

Finding

Based on our review of the best available scientific and commercial information pertaining to the Act's five threat factors, we find that the current stressors acting on the species and its habitat are not of sufficient imminence, intensity, or magnitude to make the Highlands tiger beetle warrant listing throughout the species' range at this time. Because the distribution of the species is relatively stable across its range and stressors are similar throughout the species' range, we found no concentration of stressors that suggests that the Highlands tiger beetle may be in danger of extinction or likely to become so in any portion of its range. With the documentation of 16 newly identified occupied sites, the identification of improved habitat quality, and the existing estimated adult beetle count of over 10,000 individuals in 56 sites, we find that Highlands tiger beetle is no longer in danger of extinction (endangered) or likely to become endangered within the foreseeable future (threatened) throughout all of its range or any portion of its range. Therefore, we find that listing the Highlands tiger beetle as an endangered or a threatened species is not warranted throughout all or a significant portion of its range at this time, and consequently we are removing this species from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Highlands tiger beetle, and constitutes the Service's 12-month finding on the May 11, 2004, petition to list the Highlands tiger beetle as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the Highland tiger beetle's species-specific assessment form and other supporting documents (see **ADDRESSES**, above).

Dichanthelium (=panicum) hirstii (Hirst Brothers' Panic Grass)

Previous Federal Actions

In 1975, *Panicum hirstii* (*i.e., Dichanthelium hirstii*'s former scientific name; see *Summary of Status Review,* below) was 1 of more than 3,000 vascular plants included in a Smithsonian Institution report entitled ''Report on Endangered and Threatened Plants of the United States'' (Report) that the Service subsequently treated as a petition under the Act (40 FR 27824; July 1, 1975). The **Federal Register** notice indicated that *P. hirstii* and the other plants were under consideration for listing, and the notes of endangered or threatened after each species' name solely represented the views of the authors of the Report. The Report indicated that *P. hirstii* occurred in Georgia and placed it in the endangered category. The Service did not publish another species notice of review until 1980.

In 1980, *Panicum hirstii* was considered a Category 2 candidate species (45 FR 82480; December 15, 1980). Category 2 candidate species were identified as those taxa for which

the Service possessed information indicating proposing to list the taxa was possibly appropriate, but for which conclusive data on biological vulnerability and threats sufficient to support a proposed listing rule was lacking. *Panicum hirstii* remained a Category 2 candidate species in the subsequent plant notices of review in 1983, 1985, 1990, and 1993 (48 FR 53640, November 28, 1983; 50 FR 39526, September 27, 1985; 55 FR 6184, February 21, 1990; 58 FR 51144, September 30, 1993). The Service did not publish any other notices of review for plants during this time period.

The Service revised candidate categories in 1996, and *Panicum hirstii* was not included as a candidate species under the updated categorization (61 FR 7596; February 28, 1996). The revised categories further defined a candidate species as a species for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing regulation is precluded by other higher-priority listing activities.

In 1999, the Service included *Panicum hirstii* as a new candidate species, using the updated definition, through its own internal assessment process (*i.e.,* not via a petition), and assigned it an LPN of 5, meaning it was a species with a high magnitude of nonimminent threats (64 FR 57534, October 25, 1999). *Panicum hirstii* was included in the subsequent annual CNORs with an LPN of 5 in 2001, 2002, and 2004 (66 FR 54808, October 30, 2001; 67 FR 40657, June 13, 2002; 69 FR 24876, May 4, 2004). The Service did not publish a CNOR in 2003.

On May 11, 2004, we received a petition dated May 4, 2004, from the Center for Biological Diversity and other groups and individuals requesting that the Service list *Panicum hirstii* and 225 other candidate species as endangered species or threatened species under the Act. In 2005, the Service again made a warranted-but-precluded finding for the plant, with an LPN of 5, but noted a change in its scientific name to *Dichanthelium hirstii* (70 FR 24870, May 11, 2005). In 2006 through 2014, *D. hirstii* remained a candidate with an LPN of 5 (see September 12, 2006 (71 FR 53756), December 6, 2007 (72 FR 69034), December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), November 10, 2010 (75 FR 69222), October 26, 2011 (76 FR 66370), November 21, 2012 (77 FR 69994), November 22, 2013 (78 FR 70104), and December 5, 2014 (79 FR 72450)). In 2015, *D. hirstii* was included as a candidate in the CNOR, but the LPN was elevated from 5 to 2, indicating a species with a high magnitude of imminent threats (80 FR 80584, December 24, 2015).

Background

Dichanthelium hirstii, as referenced in some literature, is a perennial, wetland-obligate grass that is currently estimated to occur in eight locations distributed across four States: New Jersey (Barkwoods Pond, Labounsky Pond, and Berlin Avenue Bogs North in Atlantic County, and Hampton Furnace Pond in Burlington County); Delaware (Assawoman Pond in Sussex County); North Carolina (Starretts Meadow and Lyman Road in Onslow County); and Georgia (Leslie Pond in Sumter County). A ninth location, in Calhoun County, Georgia, is considered historical.

Summary of Status Review

The plant that the Service has been referring to as either *P. hirstii* or *D. hirstii* has always had a complex taxonomic history, and has undergone several changes to its scientific name as understanding about its distribution and morphology has evolved. The Flora of North America (FNA) is one source of information available to the Service and is considered the taxonomic authority for plants in North America because it is a comprehensive, systematic taxonomic account of the plants of North America. While several authors have published regional flora and descriptions that recognize *Panicum hirstii*/*Dichanthelium hirstii* as a separate entity, few have published taxonomic treatments. The last taxonomic treatment was the 2003 FNA, which is a complete taxonomic treatment of the *Dichanthelium* genus and the species therein, that explicitly relegates *P. hirstii*/*D. hirstii* to a synonym of *D. dichotomum* ssp. *roanokense* (Ashe). This indicates that the plant the Service had considered a candidate species is not a valid taxon and is a component of a larger, more widespread species that appears to grow on the coastal plain from Delaware to southeastern Texas and in the West Indies. Although the Integrated Taxonomic Information System (ITIS; *http://www.itis.gov/*) reports that *Dichanthelium hirstii* is an accepted species and the Service often relies on ITIS as a reliable database source of taxonomic information, in this instance ITIS is incorrect. Given this closer review of the taxonomic history of *P. hirstii*/*D. hirstii,* the Service recognizes that we overlooked the significance of the synonymy information, and in retrospect should not have included *P. hirstii* or *D. hirstii* as a candidate species. While the 2015 published and draft documents of McAvoy *et al.* and Weakley, respectively, and the ITIS database information are more recent than the 2003 FNA's published treatment, those documents and database do not individually or collectively represent a more comprehensive systematic analysis of the plant's taxonomic status because they are not full taxonomic treatments of *Panicum* and *Dichanthelium.* Therefore, the Service considers the FNA's 2003 treatment of *Panicum* and *Dichanthelium* as representing the best available scientific and commercial information regarding the plant's taxonomic status. The FNA's treatment indicates that neither *P. hirstii* nor *D. hirstii* is considered a species, subspecies, or variety. Therefore, the best available scientific and commercial information indicates that *P. hirstii*/*D. hirstii* does not meet the Act's definition of a species.

Finding

Based on the best available scientific and commercial information, we find that *Dichanthelium hirstii* does not meet the Act's definition of ''species'' and is, therefore, not a listable entity under the Act. *Dichanthelium hirstii* was subsumed into *D. dichotomum* ssp. *roanokense* (Ashe), which ''grows on the coastal plain from Delaware to southeastern Texas and in the West Indies.'' As a result, we are removing *Dichanthelium hirstii* from the candidate list.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Hirst Brothers' panic grass, and constitutes the Service's 12-month finding on the May 4, 2004, petition to list the Hirst Brothers' panic grass as an endangered or threatened species. A detailed discussion of the basis for this finding, including a complete review of the taxonomic history, can be found in the Hirst Brothers' panic grass's species-specific assessment form and other supporting documents (see **ADDRESSES**, above).

Two Kentucky Cave Beetles (Louisville Cave Beetle (*Pseudanophthalmus troglodytes*) and Tatum Cave Beetle (*Pseudanophthalmus parvus*)

Previous Federal Actions

The Louisville cave beetle and Tatum Cave beetle were added to the Federal list of candidate species in the November 15, 1994, CNOR (59 FR 58982) as Category 2 species. Category 2 candidate species were identified as those taxa for which the Service possessed information indicating proposing to list the taxa was possibly appropriate, but for which conclusive data on biological vulnerability and threats sufficient to support a proposed listing rule was lacking. The February 28, 1996, CNOR (61 FR 7596) discontinued recognition of categories, so both species were no longer considered candidate species and were therefore removed from the candidate list.

In the October 30, 2001, CNOR, the Service re-evaluated both cave beetle species, and placed them back on the candidate list through the Service's own internal process with an LPN of 5 (66 FR 54808). The Service received a petition from the Center for Biological Diversity and others, dated May 11, 2004, to list eight cave beetles, including the Louisville cave beetle and Tatum Cave beetle, as endangered or threatened species. In the May 11, 2005, CNOR (70 FR 24870), the Service determined that listing the Louisville cave beetle and Tatum Cave beetle was warranted but precluded by higher priority listing decisions. Further, we have included both species addressed in this finding in every CNOR since 2001 (see October 30, 2001 (66 FR 54808); June 13, 2002 (67 FR 40657); May 4, 2004 (69 FR 24876); May 11, 2005 (70 FR 24870); September 12, 2006 (71 FR 53756), December 6, 2007 (72 FR 69034), December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), November 10, 2010 (75 FR 69222), October 26, 2011 (76 FR 66370), November 21, 2012 (77 FR 69994), November 22, 2013 (78 FR 70104), December 5, 2014 (79 FR 72450), and December 24, 2015 (80 FR 80584)).

Background

These two species are small (about 4 mm (0.16 in) in length), predatory cave beetles that occupy moist habitats containing organic matter transported from sources outside the cave environment. Members of the *Pseudanophthalmus* genus vary in rarity from fairly widespread species that are found in many caves to species that are extremely rare and commonly restricted to one or only a few cave habitats. The Louisville cave beetle is restricted to four caves in Jefferson County, Kentucky, while the Tatum Cave beetle is known from one cave (Tatum Cave) in Marion County, Kentucky.

Summary of Status Review

When the Louisville cave beetle and Tatum Cave beetle were identified as candidates for protection under the Act in the October 30, 2001, CNOR (66 FR 54808), the Service considered both species to be vulnerable to toxic chemical spills, discharges of large amounts of polluted water, closure or alterations of cave entrances, and the disruption of cave energy processes by highway construction and industrial, residential, and commercial development. Our general perception was that both species were vulnerable to these habitat stressors, and we suspected that these stressors were significant and the species' overall population trends were likely decreasing. We also noted the lack of State or Federal regulations to ameliorate those threats. In the May 11, 2005, CNOR (70 FR 24870), we noted both species' limited distribution and how that would increase their vulnerability to isolated events that would have only a minimal effect on more wide-ranging members of the genus *Pseudanophthalmus.* Both species were assigned an LPN of 5.

Louisville Cave Beetle

Over the last 2 years, field surveys for the Louisville cave beetle have provided new information on the species' distribution and stressors. Based on this new information, we have re-examined the species' status and re-evaluated the magnitude and imminence of its threats. Lewis and Lewis confirmed the continued presence of *P. troglodytes* in Eleven Jones Cave (a period of 20 years) and observed the species in three new caves (Sauerkraut Cave, Cave Hill Cave, and Cave Creek Cave), demonstrating that the species is more abundant and widespread than previously believed. The species was difficult to find in each of these caves (one to four individuals observed), but this is not unusual for the genus *Pseudanophthalmus,* which is often difficult to find and is frequently observed in low numbers. Population estimates or discernable trends for these populations have not been possible due to the low number of individuals observed and the difficulty in finding specimens during repeat visits. We acknowledge that caves within the species' range likely continue to be affected by many of the same stressors identified by previous investigators: reduced energy inputs, sedimentation, pollution, and human visitation. However, we have no evidence that these stressors are operative threats that are adversely affecting *P. troglodytes* at a population level.

Tatum Cave Beetle

With respect to the Tatum Cave beetle, we have no evidence suggesting that the species is still extant in Tatum Cave. The species was relatively abundant (20 individuals) in Tatum Cave when first observed by C. H. Krekeler in 1957, but the species appeared to be less common in 1965, when T. C. Barr observed only two individuals. Since 1965, extensive surveys of Tatum Cave have been completed on eight separate occasions, using search techniques similar to those used by C. H. Krekeler and T. C. Barr (*i.e.,* methodical visual searches of all available habitats). Three of these survey efforts also involved the use of baited pitfall traps (small cups buried in the substrate and baited with limburger cheese) placed in several locations within Tatum Cave for a period of one week. Despite all of these searches, no Tatum Cave beetles have been observed in Tatum Cave since the last observation by Barr in 1965 (a period of 51 years).

The Tatum Cave beetle is small in size and may be more difficult to locate than some cave organisms; however, both Krekeler and Barr were able to find the species using methodical, visual searches of suitable habitats in Tatum Cave. Subsequent researchers have used identical search methods on eight separate occasions in the exact same habitats within Tatum Cave, but no Tatum Cave beetles have been observed. Therefore, based on our review of the best available scientific and commercial information, the Service believes the Tatum Cave beetle to be extinct. We acknowledge that it is difficult, if not impossible, to verify a species' extinction. There is considerable uncertainty about the actual status of the species, and we acknowledge that, as suggested by Lewis and Lewis, there is some chance that the species remains extant but occurs in low numbers and is simply undetectable using traditional search methods. However, considering the best available scientific and commercial information, we believe that it is reasonable to conclude that the species is extinct. The Service encourages continued surveys for the Tatum Cave beetle in Tatum Cave, as time and funding allow. If the species is subsequently found to be extant, we can reevaluate its legal status under the Act in the future.

Finding

Louisville Cave Beetle

Based our review of the best available scientific and commercial information pertaining to the Act's five threat factors and our review of the species' status, we conclude that the Louisville cave beetle is not subject to the degree of threats sufficient to indicate that it is in danger of extinction (an endangered species), or likely to become endangered within the foreseeable future (a threatened species), throughout all of its range.

We evaluated the current range of the Louisville cave beetle to determine if there is any apparent geographic concentration of potential threats for this species. It has a relatively small range that is limited to four caves. We examined potential stressors including human visitation and disturbance, commercial and residential development, sources of water quality impairment, and small population size. We found no concentration of stressors that suggests that the species may be in danger of extinction in any portion of its range. Therefore, we find that listing the Louisville cave beetle as an endangered species or a threatened species under the Act throughout all or a significant portion of its range is not warranted at this time, and consequently we are removing it from candidate status.

Tatum Cave Beetle

A review of the best available scientific and commercial information, leads us to believe that the Tatum Cave beetle is extinct, and, as such, it is not eligible for listing as an endangered species or a threatened species under the Act. Therefore, we did not further evaluate whether the Tatum Cave beetle is in danger of extinction throughout its range (an endangered species), likely to become in danger of extinction throughout its range in the foreseeable future (a threatened species), or whether the species is an endangered or threatened species in a significant portion of its range.

Therefore, we find that listing the Louisville cave beetle and Tatum Cave beetle as endangered or threatened species under the Act throughout all or a significant portion of their respective ranges is not warranted at this time, and consequently we are removing both species from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Louisville cave beetle and Tatum Cave beetle, and constitutes the Service's 12-month finding on the May 11, 2004, petition to list the Louisville cave beetle and Tatum Cave beetles as endangered or threatened species under the Act. A detailed discussion of the basis for this finding can be found in the Louisville cave beetle's and Tatum Cave beetle's species-specific assessment form and other supporting documents (see **ADDRESSES**, above).

Relict Leopard Frog (*Lithobates onca*)

Previous Federal Actions

On May 9, 2002, the Service received a petition from the Center for Biological Diversity and Southern Utah Wilderness Alliance (SUWA) seeking to list the relict leopard frog and designate critical habitat, under the authority of the Act. The petition identified information regarding the species' ecology, historical and current distribution, present status, and actual and potential causes of decline.

Prior to receipt of the May 2002 petition, the Service was involved in coordinated conservation efforts for the relict leopard frog among multiple partners and was aware of the species' status. On June 13, 2002, the Service's CNOR determined the species (as *Rana onca*) warranted listing but that listing was precluded by higher priorities; therefore, it became a candidate species with an LPN of 5 (67 FR 40657).

In 2006, the species' LPN was lowered to 11, and remained at that LPN through the 2010 CNOR (see September 12, 2006 (71 FR 53756), December 6, 2007 (72 FR 69034), December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), and November 10, 2010 (75 FR 69222)). The lower priority ranking resulted from the development of the 2005 Relict Leopard Frog Conservation Agreement and Strategy (Conservation Agreement) and implementation of conservation actions by the relict leopard frog Conservation Team (Conservation Team), which led to an overall reduction in most threats and an overall improvement in the species' status. On October 26, 2011 (76 FR 66370), we changed the species' LPN to 8, due in part to the discovery of chytrid fungus (*Batrachochytrium dendrobatidis* (Bd)) in relict leopard frogs in 2010, and we maintained an LPN of 8 for the species through the 2015 CNOR (see November 21, 2012 (77 FR 69994), November 22, 2013 (78 FR 70104), December 5, 2014 (79 FR 72450), and December 24, 2015 (80 FR 80584)). In 2010, we recognized the scientific name of the relict leopard frog as *Lithobates onca* (see November 10, 2010 (75 FR 69222)).

Background

Relict leopard frogs are endemic to the Colorado, Virgin, Santa Clara, and Muddy Rivers and associated springs in Nevada, Arizona, and Utah. Relict leopard frogs appear to require habitat heterogeneity (consisting of diverse habitat types) in the aquatic and terrestrial environments. Relict leopard frogs historically occupied a variety of habitats including springs, streams, and wetlands characterized by clean, clear water with various depths, and cover such as submerged, emergent, and perimeter vegetation. Nonnative predators such as Louisiana red swamp crayfish (*Procambarus clarki*), American bullfrogs (*Lithobates catesbeiana*), and nonnative fish are associated with extirpation of relict leopard frogs.

The relict leopard frog currently occurs at 8 natural sites—three in the Northshore Springs Complex (along the base of the Muddy Mountains near the Overton Arm area of Lake Mead) and five in the Black Canyon (below Lake Mead). Natural sites are those sites that support wild populations of relict leopard frogs that were not established through translocation effort.

The Northshore Springs Complex and Black Canyon populations represent distinct relict leopard frog metapopulations, wherein each metapopulation consists of smaller, spatially separated populations that occasionally interact through the movement of individuals between them, but do not interact with the other metapopuation. Within the Northshore Springs Complex, dispersal of relict leopard frogs may be possible between Blue Point and Rogers Springs. Migration and dispersal among sites also appears likely in Black Canyon but not between the two metapopulations.

In addition to natural sites, relict leopard frogs were introduced to 15 sites, 11 of which are extant. Introduction sites are those estimated by deliberately translocating relict leopard frogs to suitable habitat within the assumed historical range. All extant natural and introduction sites occur on lands managed by the National Park Service (NPS), Bureau of Land Management (BLM), Bureau of Reclamation (BR), and the Service. There is low genetic variation within

the relict leopard frog, which may indicate a history of bottlenecking or small effective population size.

Summary of Status Review

Conservation Actions Implemented

The Conservation Team was established in March 2001, and has since met at least twice each year for the past 15 years to establish and carry forward the conservation and monitoring program for the relict leopard frog. The Conservation Team has included Federal, State, and local representatives from the Service, NPS, BLM, BR, the Environmental Protection Agency, the Nevada Department of Wildlife, the Arizona Game and Fish Department, the Utah Division of Wildlife Resources, Clark County (Nevada), the Southern Nevada Water District (including the Las Vegas Springs Preserve), the University of Nevada-Las Vegas, and the University of Nevada-Reno. The primary objective of the Conservation Team was to develop and implement the 2005 Conservation Agreement. Much conservation occurred prior to finalization of the Conservation Agreement, and the Conservation Team developed the first annual work plan in 2003. Conservation actions continue to be implemented by partners through annual work plans. Revision of the Conservation Agreement is in development with an anticipated completion date of late 2016. Part of the management effort the Conservation Team undertakes to increase population sizes and expand the distribution of the species is to collect portions of relict leopard frog egg masses from natural sites, and then captive-rear and translocate them to appropriate sites as late-stage tadpoles and juvenile frogs. The Conservation Team may augment any population, natural or introduction, as determined necessary to conserve the species.

The main relict leopard frog conservation actions, both those completed and ongoing into the foreseeable future, are:

- Remove or substantially minimize threats to extant populations and occupied habitats.
- Enhance existing habitat and/or create new habitats where feasible.
- Establish additional populations of relict leopard frogs in existing or created habitats.
- Manage relict leopard frogs and their habitats to ensure persistence in diverse aquatic ecosystems, and facilitate processes that promote self-sustaining populations.
- Monitor relict leopard frog populations.
- Investigate the conservation biology of the relict leopard frog, and use the results of such investigations to better meet the overall conservation goal and objectives.

Current Analysis of Stressors Impacting the Relict Leopard Frog

In completing our status review for the relict leopard frog, we reviewed the best available scientific and commercial information, and compiled this information in the SSA Report for the relict leopard frog. We evaluated the potential threats (identified in the SSA Report as ''stressors'' or ''potential stressors,'' and consistent with the Act's five threat factors identified in the SSA Report) that may be operative upon the relict leopard frog currently or in the future.

As required by the Act, we considered the five threat factors in assessing whether the relict leopard frog is endangered or threatened throughout all or a significant portion of its range. We examined the best scientific and commercial information available regarding the past, present, and future stressors faced by the relict leopard frog. We reviewed the information available in our files and other available published and unpublished information, and we consulted with recognized relict leopard frog species and habitat experts and other Federal, State, and tribal agencies. Listing under the Act is warranted if, based on our review of the best available scientific and commercial information, we find that the stressors to the relict leopard frog are so severe or broad in scope as to indicate that the species is in danger of extinction (endangered), or likely to become endangered within the foreseeable future (threatened), throughout all or a significant portion of its range.

In the SSA Report we evaluated each of the potential stressors for the relict leopard frog, and we determined that the following factors have impacted, or may impact individuals, specific sites, or portions of suitable habitat in the future: (1) Alteration of natural spring and groundwater systems and reduced habitat connectivity; (2) overgrowth of emergent vegetation and nonnative or invasive plants; (3) excessive disturbance due to feral horses, burro, and livestock use; (4) disease; (5) nonnative fish predation; (6) small population size; and (7) climate change, flash flood events, and wildfire. Although these stressors may continue to affect the relict leopard frog, they are not causing a population-level risk to the species now nor are they expected to do so into the foreseeable future. Overutilization and crayfish and bullfrog predation were evaluated in the SSA Report for the relict leopard frog but were found to result in no or low impacts, respectively, across the species' range. Thus, we do not discuss overutilization or predation further in this document. We have summarized the threats analysis from the SSA Report below. A complete description of those stressors and threats, and how they affect the viability of the species, is included in the SSA Report.

The effects of historical alteration of natural riverine and groundwater systems and reduced habitat connectivity to the relict leopard frog at the individual or site-specific level are ongoing and may continue into the future. However, there have not been any recent alterations of natural riverine and groundwater systems and reduced habitat connectivity on relict leopard frog populations and their habitat. Historical modification to the Colorado and Virgin rivers effectively isolated the two metapopulations of relict leopard frog, and they will most likely never be reconnected. Although the two relict leopard frog metapopulations and most relict leopard frog introduction sites are not connected, ongoing management actions by the Conservation Team minimizes population isolation through captive rearing and translocation of frogs to targeted sites. We conclude that there are effects to relict leopard frog populations and perhaps the species from historical alteration of natural riverine and ground water systems and reduced habitat connectivity, but these the effects are low in severity and do not threaten the persistence of the species.

Some sites can have overgrowth of vegetation that can have adverse effects on relict leopard frogs that reduce the extent of surface water and habitat for breeding and feeding. These effects from overgrowth of vegetation are low in severity because they are reduced by storms that remove vegetation through scouring, by manual removal, and by grazing.

Burro and cattle grazing have both degraded and improved aquatic habitat at some sites. Controlled, low-level grazing typically provides disturbance that benefits frog habitat by removing excess vegetation. If grazing increases to heavy use, habitat conditions may become degraded. Similarly, burro and cattle grazing are not having a population-level effect to the relict leopard frog now or into the future.

Disease and nonnative fish predation have been evaluated and monitored by the Conservation Team. The presence of the chytrid fungus, *Batrachochytrium dendrobatidis* (Bd) in relict leopard

frogs at Lower Blue Point Spring warrants further evaluation of its impact to the species. Although there is evidence that Bd is present in one population, there is no indication any frogs have been adversely affected by disease. The Conservation Team will continue to monitor populations for effects of disease. Any potential effects at the individual or site- specific level resulting from nonnative fish in the Northshore Springs Complex and Corn Creek are low in severity. Disease and predation are not having a population-level effect on the relict leopard frog now, and such effects are not expected to occur in the future. The Conservation Team is taking action to improve the conditions for disease and predation through conservation measures (see ''Conservation Actions Implemented,'' above).

The small population size is the focus of conservation efforts, including population augmentation and establishing introduction sites. Low numbers of individual frogs at a given site may increase risk and vulnerability of the species to other stressors. Although small population size can affect the species as a whole by reducing genetic diversity and possibly reducing the species' ability to adapt to changing environmental conditions, the best available scientific and commercial information shows that this species is capable of persisting into the foreseeable future with current population sizes and under existing levels of management by the Conservation Team. The potential for effects of small population size has been, and will continue to be, minimized by actions taken by the Conservation Team, including habitat management and a captive-rearing program that produces frogs from eggs collected in the wild. These frogs are used to establish new sites and augment both natural and introduction sites, as appropriate. Conservation Team actions continue to minimize the potential for effects of small population size, and small population effects are not expected to affect the persistence of frogs at any site or population.

Climate change effects may result in reduced spring flow, habitat loss, increased severity of storms, flooding, and increased prevalence of wildfire that could adversely affect relict leopard frog populations. Although negative effects from climate change could occur to individuals or specific sites, species-level effects would not reach a level now or into the foreseeable future to the extent that rangewide numbers and distribution would be substantially reduced. The relict leopard frog Conservation Team has been addressing these stressors in the past, and ongoing efforts are planned to continue into the future.

We considered relevant Federal, State, and tribal laws and regulations when evaluating the status of the species. Regulatory mechanisms, if they exist, may preclude the need for listing if we determine that such mechanisms adequately reduce the stressors to the species such that listing is not warranted. The effects of applicable existing regulatory mechanisms are considered in our evaluation of the stressors acting on the species. Below, we briefly review those regulatory mechanisms aimed to help reduce stressors to the relict leopard frog and its habitat.

The relict leopard frog is protected by the State laws of Nevada, Arizona, and Utah. Nevada Revised Statutes (NRS) 533.367 states that before a person may obtain a right to the use of water from a spring or water that has seeped to the surface of the ground, that person must ensure that wildlife which customarily uses the water will have access to it. However, the State Engineer, who oversees all water rights, may waive this requirement for a domestic use of water (NRS 533.367). Authority provided by NRS 503.587 allows the Wildlife Commission to use its authority to manage land to carry out a program for conserving, protecting, restoring and propagating selected species of native fish, wildlife, and other vertebrates and their habitat, which are threatened with extinction and destruction. Also, habitat protection for the relict leopard frog is provided by Nevada Administrative Code 504.520, which prohibits alteration of a wetland or stream to the detriment of wildlife without a permit.

The Arizona Game and Fish Department (AGFD) classified the relict leopard frog as a Tier 1A Species of Greatest Conservation. Commission Order 41 of the AGFD regulations prohibits collection or hunting of relict leopard frogs, except under the authority of a special permit. Protection under Commission Order 41 provides protection to individual frogs, but not to habitat.

The Utah Division of Wildlife Resources classified the relict leopard frog as a Sensitive Species in Utah. State of Utah Rule 657–3 prohibits the collection, importation, and possession of relict leopard frogs without a certificate of registration but provides no protection of habitat.

All populations of the relict leopard frog occur on Federal land (Service, BLM, NPS, BR). Existing Federal laws, such as the NPS Organic Act of 1916, as amended (16 U.S.C. 1 *et seq.*), National Environmental Policy Act of 1976 (NEPA; 42 U.S.C. 4321 *et seq.*), and the National Wildlife Refuge System Improvement Act of 1997 (Pub. L. 105–57), have facilitated conservation efforts that have reduced the threats to the relict leopard frog. NPS and BLM manage all extant relict leopard frog sites except Pupfish Refuge and Corn Creek. The Pupfish Refuge occurs in a protected area of Hoover Dam and Corn Creek, and is an experimental population on a Service National Wildlife Refuge. NPS provides the captive-rearing facility, which is important for establishing and augmenting relict leopard frog populations.

BLM uses their regulatory mechanisms and authority to provide sites to establish new populations of relict leopard frog, a BLM sensitive species, and complete habitat improvements to benefit the species.

BLM's manual (6840—Special Status Species Management) establishes policy for management of BLM sensitive species under the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*). BLM sensitive species will be managed consistent with species and habitat management objectives in land use and implementation plans to promote their conservation and to minimize the likelihood and need for listing under the Act. BLM is a member of the Conservation Team and implements or authorizes conservation actions for the conservation of the relict leopard frog.

The National Wildlife Refuge System Improvement Act of 1997 provides the mission for the Service's wildlife refuges to administer a national network of lands and waters for the conservation, management, and where appropriate, restoration of the fish, wildlife, and plant resources and their habitats for the benefit of present and future generations of Americans. Each refuge is required to fulfill this mission and provide for the conservation of fish, wildlife, and plants, and their habitats within the Refuge System. Within the range of the relict leopard frog, the Desert National Wildlife Refuge would complement efforts of States and other Federal agencies to conserve fish and wildlife and their habitats, and to assist in the maintenance of adequate water quantity and water quality to fulfill the mission. Prior to release of relict leopard frogs at Corn Creek, the Refuge eradicated bullfrogs and substantially improved conditions that created habitat for the relict leopard frog. The Refuge manager provides access to biologists to perform releases of frogs and monitor the population. The Refuge continues to

control crayfish, maintain habitat conditions by removing excess vegetation, and inform the public about the species.

NPS and BLM authorities and regulatory mechanisms have successfully provided or facilitated conservation of the species (see ''Conservation Actions Implemented,'' above). NPS, BLM, BR, and the Service are signatories on the Conservation Agreement and actively involved in all actions of the Conservation Team. Each agency coordinates development of annual work plans and utilizes their authority to implement conservation actions that benefit the species. Federal authorities and regulatory mechanisms have successfully provided or facilitated conservation of the species.

We did not find any stressors examined under the Act's threat factors A, B, C, and E to rise to the level of a threat that would cause us to determine listing of the relict leopard frog is warranted. Based on our review of the stressors combined with the beneficial effects that the various conservation efforts and regulatory mechanisms provided to the species, we find that the existing regulatory mechanisms (Factor D) are adequate to address the stressors currently impacting the relict leopard frog and its habitat.

Regarding cumulative effects, there are potential stressors that may act together to affect relict leopard frogs at certain sites. Overgrowth of vegetation, nonnative plants and predators, and disease acting on small populations may adversely affect certain populations concurrently. Flash floods or wildfire may adversely affect a site at the same time as nonnative plants and predators. Reduced habitat connectivity adversely affects sites with small populations at the same time as overgrowth of vegetation, and nonnative plants and predators. Climate change may affect a site at the same time as grazing, wildfire, and flash floods. However, after evaluating the cumulative effects, we conclude that the magnitude of cumulative effects to the relict leopard frog is low to moderate. Most stressors adversely affect the relict leopard frog in a single geographic area due to the isolated distribution of most sites. Although individuals may be affected by cumulative effects in a single geographic area, there would not be population level effects to the species.

Multiple stressors on relict leopard frogs may act synergistically, exacerbating effects greater than what may be observed by individual stressors. The effects of climate change may increase the number and frequency of wildfires and flash flood events. The presence of nonnative plants can make the effects of excess vegetation worse. Overgrowth of vegetation may reduce habitat for breeding, potentially making small populations smaller. Disease and nonnative predators such as bullfrogs, crayfish, and fishes may also exacerbate the effects of small populations by removing frogs. We determined that synergistic effects may occur, although they are expected to be low in magnitude. Most individual stressors adversely affect the relict leopard frog in a single geographic area, due to the isolated distribution of most sites. Although individuals may be affected by synergistic effects in a single geographic area, there would not likely be population-level effects to the species.

To minimize or mitigate effects from stressors affecting the relict leopard frog, the Conservation Team will continue monitoring populations and reintroducing frogs to sites should they become greatly reduced in numbers or extirpated due to the effects of one or more stressors.

Finding

Based on our review of the best available scientific and commercial information pertaining to the Act's five threat factors, we find that the stressors acting on the species and its habitat, either singly or in combination, are not of sufficient imminence, intensity, or magnitude to indicate that the relict leopard frog is in danger of extinction (an endangered species) throughout all of its range, or likely to become endangered within the foreseeable future (a threatened species) throughout all of its range.

Populations of relict leopard frogs are improving due to past conservation actions and current efforts to re-establish and increase naturally-occurring and reintroduced populations. Current and ongoing habitat management, establishment of new sites, and restoration activities have made substantial progress since their inception and are continuing into the future. We have determined that the number of frogs and habitat conditions at individual sites change from year to year and may vary widely, but the rangewide status of the species is stable or increasing.

After determining the species is not endangered or threatened throughout all of its range, we then conducted an analysis to determine if it was endangered or threatened throughout a significant portion of the species' range. To do this, we evaluated whether there was any portion of the species' range where threats were concentrated such that the species in that portion would be endangered or threatened, and that losing that portion of the range would cause the remainder of the species to be endangered or threatened. Once we determined that there was no geographic concentration of threats that would cause any portion of the species' range to be at greater risk of extinction, then we could conclude that no portion warranted further consideration. Therefore, we find that listing the relict leopard frog as an endangered or a threatened species throughout all of or a significant portion of its range under the Act is not warranted at this time, and, consequently, we are removing it from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the relict leopard frog, and constitutes the Service's 12-month finding on the May 8, 2002, petition to list the relict leopard frog as an endangered or threatened species. A detailed discussion of the basis for this finding, including the many effective conservation measures completed by the Conservation Team, can be found in the relict leopard frog's species-specific assessment form, SSA Report, and other supporting documents (see **ADDRESSES**, above).

Sicklefin Redhorse Sucker (*Moxostoma* sp.)

Previous Federal Actions

The sicklefin redhorse sucker was originally made a candidate species in the May 11, 2005, CNOR (70 FR 24870), and it was included in the subsequent CNORs through 2015 (see September 12, 2006 (71 FR 53756), December 6, 2007 (72 FR 69034), December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), November 10, 2010 (75 FR 69222), October 26, 2011 (76 FR 66370), November 21, 2012 (77 FR 69994), November 22, 2013 (78 FR 70104), and December 5, 2014 (79 FR 72450)).

On April 20, 2010, we received a petition from the Center for Biological Diversity, requesting that the Service list 404 aquatic species as endangered or threatened species under the Act,

including the sicklefin redhorse sucker. The petition included supporting information regarding the species' taxonomy and ecology, historical and current distribution, present status, and actual and potential causes of decline. In a partial 90-day finding on the petition to list 404 species, published on September 27, 2011 (76 FR 59836), the Service reaffirmed the existing candidate status of the sicklefin redhorse sucker.

Background

The sicklefin redhorse sucker (*Moxostoma sp.*), a freshwater fish species, can grow to a length of approximately 650 mm (roughly 25.6 in). It has an elongate, somewhat compressed body and a highly falcate (sickle shaped) dorsal fin (back fin). Its body is olive-colored, with a coppery or brassy sheen; its lower fins (pectoral, pelvic, and anal fins) are primarily dusky to dark, often tinted yellow or orange and pale edged; the caudal fin (tail fin) is mostly red; and its dorsal fin is olive in color, sometimes partly red.

Although the sicklefin redhorse sucker is now known to have been collected in 1937 (based upon preserved specimens collected at the then-unimpounded mouth of Forney Creek near its confluence with the Tuckasegee River), it was not recognized as a potentially distinct species until 1992, when Dr. Robert Jenkins obtained and examined two specimens that had been collected in 1981 and 1982 from the Little Tennessee River by Dr. Edward Menhinick (University of North Carolina at Charlotte, Charlotte, North Carolina). Based on the characteristics of the specimens' lower lips, dorsal fins, and pharyngeal teeth, Jenkins recognized the species as possibly a previously unidentified species or a hybrid of the smallmouth redhorse (*M. breviceps*) and the river redhorse (*M. carinatum*). Subsequent detailed morphological and behavioral studies and genetic studies have concluded that the sicklefin redhorse sucker is, in fact, a distinct species. The Service has reviewed the available taxonomic literature, and is not aware of any challenges to the validity of this conclusion.

The species is currently known to occupy cool to warm, moderate-gradient creeks and rivers and, during at least parts of its early life, large reservoirs. In streams, adults of the species are generally associated with moderate to fast currents, in riffles, runs, and well-flowing pools, while juveniles show a preference for moderate to deep pools with slow currents and large boulder crevice cover. Adults feed and spawn over gravel, cobble, boulder, and bedrock substrates with no, or very little, silt overlay.

Past and recent collection records of the sicklefin redhorse sucker, together with what is known about the habitat utilization of the species, indicate that the sicklefin redhorse sucker once inhabited the majority, if not all, of the rivers and large creeks in the Blue Ridge portion of the Hiwassee and Little Tennessee River systems in North Carolina, Tennessee, and Georgia. Currently, there are only two metapopulations of the sicklefin redhorse sucker known to remain: One in the Hiwassee River system and one in the Little Tennessee River system. Estimated occupied stream habitat in the Hiwassee river systems totals about 53.0 river miles (rm). However, use of various streams/stream reaches within this total appears to be seasonal. Available information indicates that the sicklefin redhorse sucker uses Brasstown Creek, Hanging Dog Creek, Beaverdam Creek, Nottely River, and the mid and upper reaches of the Valley River, primarily for spawning. No spawning or courting behavior was observed within the mainstem of the Hiwassee River; the mid and lower Hiwassee River or lower reaches of the spawning tributaries primarily from the post-spawning period through the fall and early winter; or the lower un-impounded reaches of the Hiwassee River, and to a lesser extent, the lower Valley River, during the winter months.

The Little Tennessee River system metapopulation of the sicklefin redhorse sucker includes a total of approximately 59.15 rm of creek and river reaches plus near-shore areas of Fontana Reservoir, including: (1) The main stem of the Little Tennessee River in Macon and Swain Counties, North Carolina, between the Franklin Dam and Fontana Reservoir (approximately 23.2 rm), and its tributaries, Burningtown Creek (approximately 5.5 rm) and Iotla Creek (approximately 0.1 rm) in Macon County, North Carolina; (2) the main stem of the Tuckasegee River in Swain and Jackson Counties, North Carolina, from approximately rm 27.5, downstream to Fontana Reservoir (approximately 27.5 rm), and its tributaries, Forney Creek (mouth of the creek), Deep Creek (approximately 2.35 rm), and the Oconaluftee River below the Bryson Dam (also sometimes referred to as the Ela Dam) (approximately 0.5 rm), in Swain County, North Carolina; and (3) sub-adults in the near shore portions of Fontana Reservoir, Swain County, North Carolina.

Summary of Status Review

In completing our status review, we reviewed the best available scientific and commercial information and compiled this information in the SSA Report for the sicklefin redhorse sucker. For our finding, we evaluated potential stressors related to the sicklefin redhorse sucker and its habitat. The stressors we analyzed were: (1) Hydroelectric operations, inadequate erosion/sedimentation control during agricultural, timbering, and construction activities; (2) runoff and discharge of organic and inorganic pollutants from industrial, municipal, agricultural, and other point and nonpoint sources; (3) habitat alterations associated with channelization and instream dredging/mining activities; (4) predation and habitat suitability impacts by nonnative species; (5) fragmentation and isolation of surviving populations; and (6) other natural and human-related factors that adversely modify the aquatic environment. Associated with the status review for this 12-month finding, we conducted an analysis of the Candidate Conservation Agreement (CCA) for the Sicklefin Redhorse Sucker under the Service's Policy for Evaluation of Conservation Efforts When Making Listing Decisions (PECE policy), published in the **Federal Register** on March 28, 2003 (68 FR 15100), and found that the CCA does meet the PECE policy criteria for certainty of implementation and certainty of effectiveness.

A number of factors likely contributed to a reduction in the species' historical range and may have affected population dynamics within the existing occupied stream reaches. The construction of hydroelectric dams fragmented populations, confining spawning activity only to river reaches accessible from the two reservoirs where this species is thought to reside during the juvenile stage of its life cycle. The sicklefin redhorse sucker also appears to be absent from several reaches of unimpounded river habitat where it was likely extirpated by degradation of the habitat or by cold water from hypolimnetic (deepwater that remains perpetually cold) discharges or hydropeaking (releasing frequent, large discharge pulses of water) for hydropower production. The introduction of blueback herring (*Alosa aestivalis*) into the habitat occupied by the sicklefin redhorse sucker was also considered a potential threat to future population stability in past candidate assessments.

Upon further review of the information related to the factors

believed to be affecting the species at present, it appears many of them were largely historical, were less significant than previously thought, have been mitigated, or could be managed to alleviate many of the effects on the species. The sicklefin redhorse sucker likely experienced substantial range contraction associated with dam construction, power generation, and historical habitat degradation early in the 20th century, but the remaining populations appear to have stabilized within the present conditions and are successfully spawning and recruiting in four primary river drainages accessible from Hiwassee and Fontana Reservoirs.

In the future, we expect human population growth and land development to be primary factors affecting habitat quality in the range of the sicklefin redhorse sucker. However, compared to historical land use effects, we expect the effect of these future activities to be minimized by more stringent State and local land quality regulations, such as are required by current regulations for land development and water quality, and a trend of diminishing agriculture in the area. Improvements in land use practices are likely attributable to the modern regulatory environment that provides protection to the stream environment. The Fish and Wildlife Coordination Act of 1934 (16 U.S.C. 661 *et seq.*), North Carolina Environmental Policy Act of 1971, Clean Water Act of 1972 (33 U.S.C. 1251 *et seq.*), North Carolina Sediment and Pollution Control Act of 1973, Georgia Erosion and Sedimentation Act of 1975, as well as other regulatory actions, were enacted to control the effects of land development and pollution on the aquatic environment. Historical records indicate that the existing populations of the sicklefin redhorse sucker have persisted through significant agricultural land disturbance that resulted in considerable sedimentation of its habitat, indicating that the sicklefin redhorse sucker is likely able to tolerate moderate land disturbance. Rural development and the growth of several small towns within the range of the sicklefin redhorse sucker appear to be the dominant forms of land use disturbance. Rural development is limited in certain areas due to large portions of the watershed that are permanently protected by inclusion in the Nantahala and Chattahoochee National Forests. The region is currently experiencing a trend of diminishing agricultural land use, indicating that widespread conversion to farmland is not likely. Commercial development is likely to be limited by a lack of large metropolitan areas or interstate highways that would facilitate rapid growth. The trend of high suspended sediment yield in the range of the sicklefin redhorse sucker appears to have improved over the last few decades. Increasing environmental regulation, greater public awareness, and the actions of governmental and nongovernmental organizations to improve water quality conditions have resulted in considerable improvements in suspended sediment rates. Therefore, we expect existing regulations for land development and water quality to adequately maintain habitat quality, and we anticipate that the species is likely to persist into the future even with the expected increase in development.

The sicklefin redhorse sucker is provided additional protection by State endangered species regulations and association with other federally listed species. It is listed as threatened by the State of North Carolina and endangered by the State of Georgia. Both States prohibit direct take of the species and the collection of the fish for scientific purposes without a valid State collecting permit. In the unimpounded portions of the mainstems of the Little Tennessee River and Tuckasegee River where the sicklefin redhorse sucker occurs, the species' habitat is indirectly provided Federal protection through the Act, where the mainstem portions of both of these rivers are designated as critical habitat for the endangered Appalachian elktoe (*Alasmidonta raveneliana*) (a mussel). In addition to the Appalachian elktoe, the portion of the Little Tennessee River where the sicklefin redhorse sucker occurs also supports populations of the endangered little-wing pearlymussel (*Pegias fabula*) and the threatened spotfin chub (*Erimonax monachus*) and is also designated as critical habitat for the spotfin chub.

Substantial public land ownership in the watersheds occupied by the sicklefin redhorse sucker provides partial protection to the watershed. Approximately 43 percent of the land adjacent to waterways occupied this species is owned by State and Federal agencies or by nongovernmental conservation organizations. On these conserved properties, land development is prohibited, providing protection to buffers and potentially improving water quality throughout the watershed. Most of the land surrounding Hiwassee and Fontana Lakes is publicly owned, limiting shoreline development and protecting the near shore habitat used by juvenile sicklefin redhorse suckers. The Eastern Band of Cherokee Indians has management jurisdiction over a portion of the lands within both the Hiwassee River and Tuckasegee River watersheds, and tribal water quality ordinances protect habitat and water quality. Approximately 65 percent of the occupied area of the Little Tennessee River is protected from development by inclusion in the Needmore Game Lands. Along the other three major spawning tributaries, most of the land is privately held and does not have any restriction on land development.

When the sicklefin redhorse sucker was elevated to candidate status in 2005, the blueback herring, an invasive predator species, had been inadvertently introduced into the Hiwassee Reservoir, a major waterbody supporting the sicklefin redhorse sucker. At the time, predation of young sicklefin redhorse sucker by blueback herring was an unassessed threat. However, a recent study examining the gut contents of blueback herring in the Valley River and Hiwassee Reservoir failed to find any sicklefin redhorse suckers among the samples. It appears that the sicklefin redhorse sucker may naturally avoid predation by blueback herring by spawning farther upstream than typical foraging habitat for blueback herring. In the spring of 2016, blueback herring were collected from Fontana Reservoir, the other reservoir important for sicklefin redhorse sucker recruitment. Further investigation is required to determine the degree of impact the presence of blueback herring in Fontana Reservoir poses to the sicklefin redhorse sucker, but the distance to spawning sites upstream of Fontana Reservoir is similar to the distance in the Hiwassee Reservoir, suggesting that blueback herring will be similarly separated from the hatching sicklefin redhorse sucker fry during the time when they are most likely to be present in the reservoir. Collections in the Hiwassee River system in 2014–2015 produced many young adult/late juvenile sicklefin redhorse suckers that have clearly recruited since the herring invasion, even while juvenile walleye and white bass steeply declined immediately after the invasion, suggesting the blueback herring is not preventing successful recruitment of sicklefin redhorse suckers. Therefore, recent observations indicate that blueback herring have not proven to be a threat to the sicklefin redhorse sucker as once feared.

Many of the stressors that may affect the sicklefin redhorse sucker in the future can be further minimized by conservation actions carried out under the recently signed CCA among the Service, North Carolina Wildlife

Resources Commission, Duke Energy Carolinas, Eastern Band of Cherokee Indians, Tennessee Valley Authority, and Georgia Department of Natural Resources. A primary goal of the CCA is to expand the range of this species upstream of barrier dams to repopulate stream reaches that were formerly degraded, but currently appear suitable. Expanding the range of the sicklefin redhorse sucker into the upper sections of these watersheds will provide a greater variety of available habitat, allowing the species to more easily adjust to temporary effects of construction and landscape alteration, and providing more opportunities to use areas of refuge during periods of adverse conditions, such as periods of high temperature or increased flow. Accessibility to more suitable habitat will increase the number of available spawning sites, increasing the opportunities for successful recruitment, and will provide alternative spawning areas should some spawning sites become unsuitable. Successful reintroduction will increase the carrying capacity of the sicklefin redhorse sucker by providing the species with additional riverine habitat as well as access to additional reservoirs to serve as juvenile rearing habitat. The SSA Report for the sicklefin redhorse sucker noted that threats (*i.e.,* factors affecting the species) could be exacerbated by climate change or interaction among the threats. However, the SSA Report's evaluation of all of the threats facing this species indicates that the existing populations are stable and are likely to remain stable in most of the plausible future scenarios. In addition, while populations are currently stable and likely to remain so, under the CCA's management framework, the parties will work collaboratively to address threats in a way that reduces the likelihood that they will negatively affect the future viability of the species.

Finding

Based on our review of the best available scientific and commercial information pertaining to the Act's five threat factors, we find that the stressors acting on the species and its habitat, either singly or in combination, are not of sufficient imminence, intensity, or magnitude to indicate that the sicklefin redhorse sucker is in danger of extinction (an endangered species), or likely to become endangered within the foreseeable future (a threatened species), throughout all of its range. This finding is based on stability of existing populations, re-evaluation of threats that are likely to affect the populations in the future, and development of a CCA that ensures the continued participation by all stakeholders in a focused effort to address and mitigate potential threats while expanding the range and population health of the species. Additionally, we evaluated the current range of the sicklefin redhorse sucker to determine if there is any apparent geographic concentration of potential threats for the species. The current range of the species is relatively small and limited to two river systems in western North Carolina and northwestern Georgia. We examined potential threats from: (1) Hydroelectric operations, inadequate erosion/sedimentation control during agricultural, timbering, and construction activities; (2) runoff and discharge of organic and inorganic pollutants from industrial, municipal, agricultural, and other point and nonpoint sources; (3) habitat alterations associated with channelization and instream dredging/mining activities; (4) predation and habitat suitability impacts by nonnative species; (5) fragmentation and isolation of surviving populations; and (6) other natural and human-related factors that adversely modify the aquatic environment. We found no portions of the species' range where potential threats are significantly concentrated or substantially greater than in other portion of its range so as to suggest that the species may be in danger of extinction in a portion of its range. Therefore, we find that factors affecting the sicklefin redhorse sucker are essentially uniform throughout its range, indicating no portion of the range warrants further consideration of possible endangered or threatened status under the Act. Therefore, we find that listing the sicklefin redhorse sucker as an endangered or a threatened species under the Act is not warranted throughout all or a significant portion of its range at this time, and consequently we are removing it from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the sicklefin redhorse sucker, and constitutes the Service's 12-month finding on the April 20, 2010, petition to list the sicklefin redhorse sucker as an endangered or threatened species. A detailed discussion of the basis for this finding, including the PECE policy analysis of the CCA, can be found in the sicklefin redhorse sucker's species-specific assessment form, SSA Report, and other supporting documents (see **ADDRESSES,** above).

Stephan's Riffle Beetle (*Heterelmis stephani*)

Previous Federal Actions

Stephan's riffle beetle (*Heterelmis stephani*) was designated as a Category 2 candidate in the notice published in the **Federal Register** on May 22, 1984, at 49 FR 21664. Category 2 candidate species were identified as those taxa for which the Service possessed information indicating proposing to list the taxa was possibly appropriate, but for which conclusive data on biological vulnerability and threats sufficient to support a proposed listing rule was lacking. The February 28, 1996, CNOR (61 FR 7596) discontinued recognition of categories, so this species was no longer considered a candidate species. In the June 13, 2002, CNOR (67 FR 40657), Stephan's riffle beetle was designated as a candidate species as currently defined, with an LPN of 5. On May 11, 2004, we received a petition dated May 4, 2004, from the Center for Biological Diversity, requesting that 225 plants and animals, including Stephan's riffle beetle, be listed as endangered species under the Act and critical habitat be designated. In response to the May 4, 2004, petition to list Stephan's riffle beetle as an endangered species, we published a warranted-but-precluded 12-month finding in the **Federal Register** on May 11, 2005 (70 FR 24870). Subsequent warranted-but-precluded 12-month findings were published on September 12, 2006 (71 FR 53756), December 6, 2007 (72 FR 69034), December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), November 10, 2010 (75 FR 69222), October 26, 2011 (76 FR 66370), November 21, 2012 (77 FR 69994), November 22, 2013 (78 FR 70104), December 5, 2014 (79 FR 72450), and December 24, 2015 (80 FR 80584).

Background

Stephan's riffle beetle is one of five known species in the genus *Heterelmis* found in the United States. Historically, Stephan's riffle beetle occurred in Santa Cruz and Pima Counties, Arizona, at two known locations: Bog Springs Campground and Sylvester Spring in

Madera Canyon. Stephan's riffle beetle is no longer found at the Bog Springs Campground location, as the habitat there no longer exists. Stephan's riffle beetle has not been collected or documented since 1993, despite the Service's surveying for the species at the one remaining known location, Sylvester Spring, and at numerous other nearby locations with potential habitat. Based on our review of the best available scientific and commercial information, we believe that the Stephan's riffle beetle is extinct.

The preponderance of Stephan's riffle beetle specimens have been documented in artificial habitat created by a water tank's leaking pipeline and overflow at the Bog Springs Campground. Only two specimens have ever been documented from Sylvester Spring, the only relatively intact spring habitat remaining where the species was known to exist. Historically, Stephan's riffle beetle may have only occupied Sylvester and Bog Springs, and populations may have started declining when water from springs in Madera Canyon was first captured in concrete boxes and piped to divert water for domestic and recreational water supplies. Up until 1993, when Stephan's riffle beetle was last detected, the species appears to have existed only in extremely low numbers within Sylvester Spring, making it very difficult to detect, in contrast to the relatively large numbers collected in 1979 at the Bog Springs Campground site. The species has not been documented as extant since 1993, 23 years ago, when one individual was found at Sylvester Spring as part of a specific effort to survey for Stephan's riffle beetle in Madera Canyon.

Beginning in 2012, the Service surveyed Sylvester Spring, the one remaining known population location for Stephan's riffle beetle, and seven other locations with potential habitat on multiple occasions. The most intensive survey efforts occurred at Sylvester Spring and Bog Springs, the water source for the extirpated Bog Springs Campground population. Three different survey methods were used in an effort to find the species, and no Stephan's riffle beetles were found. While Stephan's riffle beetle is small in size (and therefore difficult to find), adult beetles, if present, should be detected regardless of the time of year surveyed based on their life history (multi-year metamorphosis and relatively long life span). Therefore, based on the best available scientific and commercial information, the Service believes Stephan's riffle beetle to be extinct.

Summary of Status Review

The SSA Report for Stephan's riffle beetle is a summary of the information assembled and reviewed by the Service and incorporates the best available scientific and commercial information for this species. Our analysis leads us to believe Stephan's riffle beetle is extinct. Species extinction is difficult, if not impossible, to prove, and the Service has no policy specifically defining the level of information necessary to conclude that a species should be considered extinct. For any species there is uncertainty in drawing a conclusion of extinction. For the Stephan's riffle beetle, we have carefully assessed the best scientific and commercial information available regarding the current status of the species. The biological information we reviewed and analyzed as the basis for our findings is documented in the SSA Report. Our analysis of this information found that there has been no confirmation of the existence of the Stephan's riffle beetle in more than 23 years, despite multiple survey efforts since 2012 in known and potential habitat where other riffle beetles were documented, across multiple seasons, and using a variety of survey methods. The type locality consisting of a leaking pipeline to a water storage tank, where the largest number of Stephan's riffle beetle was collected, no longer exists. The Service surveyed the only remaining site at which Stephan's riffle beetle had been documented, Sylvester Spring, on numerous occasions with different survey methods. Despite these efforts, we have been unable to confirm the existence of the species.

Finding

Our review of the best available scientific and commercial information leads us to believe that the Stephan's riffle beetle is extinct, and, as such, it is not eligible for listing as an endangered or threatened species under the Act. Although the Act does not directly address the situation of considering a species for listing where the best available information indicates that the species is likely already extinct, the purpose of the Act is to prevent species from becoming extinct. If we believe the species is already extinct, by definition, the species cannot be in danger of, or likely to become in danger of, extinction. Therefore, we did not further evaluate whether Stephan's riffle beetle is in danger of extinction throughout its range (an endangered species), is likely to become in danger of extinction throughout its range in the foreseeable future (a threatened species), or is an endangered or threatened species in a significant portion of its range. We find that listing Stephan's riffle beetle as an endangered or a threatened species under the Act is not warranted throughout all or a significant portion of its range, and consequently we are removing it from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Stephan's riffle beetle and constitutes the Service's 12-month finding on the May 4, 2004, petition to list the Stephan's riffle beetle as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the Stephan's riffle beetle's species-specific assessment form, SSA Report, and other supporting documents (see **ADDRESSES**, above).

New Information

We request that you submit any new information concerning the taxonomy, biology, ecology, status of, or stressors to the Huachuca-Canelo population of the Arizona treefrog, the Arkansas darter, black mudalia, Highlands tiger beetle, *Dichanthelium (=panicum) hirstii* (Hirst Brothers' panic grass), two Kentucky cave beetles (Louisville cave beetle and Tatum Cave beetle), relict leopard frog, sicklefin redhorse sucker, and Stephan's riffle beetle to the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**, whenever it becomes available. New information will help us monitor these species and encourage their conservation. We encourage local agencies and stakeholders to continue cooperative monitoring and conservation efforts for these species. If an emergency situation develops for any of these species, we will act to provide immediate protection.

References Cited

Lists of the references cited in the petition findings are available on the Internet at *http://www.regulations.gov* and upon request from the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**.

Authors

The primary authors of this document are the staff members of the Unified Listing Team, Ecological Services Program.

Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 26, 2016.

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2016–24142 Filed 10–5–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE935

Fisheries of the Exclusive Economic Zone Off Alaska; Exchange of Flatfish in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is exchanging unused flathead sole Community Development Quota (CDQ) for yellowfin sole CDQ acceptable biological catch (ABC) reserves in the Bering Sea and Aleutian Islands management area. This action is necessary to allow the 2016 total allowable catch of yellowfin sole in the Bering Sea and Aleutian Islands management area to be harvested.

DATES: Effective October 6, 2016 through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands management area (BSAI) according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2016 flathead sole and yellowfin sole CDQ reserves specified in the BSAI are 1,617 metric tons (mt), and 16,933 mt as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016) and following revision (81 FR 64782, September 21, 2016). The 2016 flathead sole and yellowfin sole CDQ ABC reserves are 5,472 mt and 5,719 mt as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016) and following revision (81 FR 64782, September 21, 2016).

The Aleutian Pribilof Island Community Development Association has requested that NMFS exchange 80 mt of flathead sole CDQ reserves for 80 mt of yellowfin sole CDQ ABC reserves under § 679.31(d). Therefore, in accordance with § 679.31(d), NMFS exchanges 80 mt of flathead sole CDQ reserves for 80 mt of yellowfin sole CDQ ABC reserves in the BSAI. This action also decreases and increases the TACs and CDQ ABC reserves by the corresponding amounts. Tables 11 and 13 of the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016), and following revision (81 FR 64782, September 21, 2016), are revised as follows:

TABLE 11—FINAL 2016 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH, AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

Sector	Pacific ocean perch			Flathead sole	Rock sole	Yellowfin sole
	Eastern Aleutian district	Central Aleutian district	Western Aleutian district	BSAI	BSAI	BSAI
TAC	7,900	7,000	9,000	16,390	55,180	150,530
CDQ	845	749	963	1,537	5,215	17,013
ICA	200	75	10	5,000	6,000	3,500
BSAI trawl limited access	685	618	161	0	0	14,979
Amendment 80	6,169	5,558	7,866	9,853	43,965	115,038
Alaska Groundfish Cooperative	3,271	2,947	4,171	1,411	11,129	43,748
Alaska Seafood Cooperative	2,898	2,611	3,695	8,442	32,836	71,290

Note: Sector apportionments may not total precisely due to rounding.

TABLE 13—FINAL 2016 AND 2017 ABC SURPLUS, COMMUNITY DEVELOPMENT QUOTA (CDQ) ABC RESERVES, AND AMENDMENT 80 ABC RESERVES IN THE BSAI FOR FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE

[Amounts are in metric tons]

Sector	2016 Flathead sole	2016 Rock sole	2016 Yellowfin sole	2017 Flathead sole	2017 Rock sole	2017 Yellowfin sole
ABC	66,250	161,100	211,700	64,580	145,000	203,500
TAC	16,390	55,180	150,530	21,000	57,100	144,000
ABC surplus	49,860	105,920	61,170	43,580	87,900	59,500
ABC reserve	49,860	105,920	61,170	43,580	87,900	59,500
CDQ ABC reserve	5,552	12,023	5,639	4,663	9,405	6,367
Amendment 80 ABC reserve	44,308	93,897	55,531	38,917	78,495	53,134

TABLE 13—FINAL 2016 AND 2017 ABC SURPLUS, COMMUNITY DEVELOPMENT QUOTA (CDQ) ABC RESERVES, AND AMENDMENT 80 ABC RESERVES IN THE BSAI FOR FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE—Continued

[Amounts are in metric tons]

Sector	2016 Flathead sole	2016 Rock sole	2016 Yellowfin sole	2017 Flathead sole	2017 Rock sole	2017 Yellowfin sole
Alaska Groundfish Cooperative for 2016 [1]	4,145	22,974	24,019	n/a	n/a	n/a
Alaska Seafood Cooperative for 2016 [1]	40,163	70,923	31,512	n/a	n/a	n/a

[1] The 2017 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the flatfish exchange by the Aleutian Pribilof Island Community Development Association in the BSAI. Since these fisheries are currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 30, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 3, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–24185 Filed 10–5–16; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE932

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Atka Mackerel in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is reallocating the projected unused amount of the 2016 Atka mackerel incidental catch allowance (ICA) for the Bering Sea subarea and Eastern Aleutian district (BS/EAI) to the Amendment 80 cooperative allocations in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to allow the 2016 total allowable catch of Atka mackerel in the BSAI to be fully harvested.

DATES: Effective 1200 hrs Alaska local time (A.l.t.), October 3, 2016 through 2400 hrs, A.l.t., December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2016 Atka mackerel ICA for the BS/EAI is 1,000 metric tons (mt) and 2016 Atka mackerel total allowable catch allocated to the Amendment 80 cooperatives is 21,895 mt as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016).

The Administrator, Alaska Region, NMFS, has determined that 775 mt of the Atka mackerel ICA for the BS/EAI will not be harvested. Therefore, in accordance with § 679.91(f), NMFS reallocates 775 mt of Atka mackerel from the BS/EAI ICA to the Amendment 80 cooperatives in the BSAI. In accordance with § 679.91(f), NMFS will reissue cooperative quota permits for the reallocated Atka mackerel following the procedures set forth in § 679.91(f)(3).

The harvest specifications for Atka mackerel included in the harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016) are revised as follows: 225 mt of Atka mackerel for the BS/EAI ICA and 22,670 mt of Atka mackerel for the Amendment 80 cooperative allocations in the BS/EAI. Table 6 is revised and republished in its entirety as follows:

TABLE 6—FINAL 2016 SEASONAL AND SPATIAL ALLOWANCES, GEAR SHARES, CDQ RESERVE, INCIDENTAL CATCH ALLOWANCE, AND AMENDMENT 80 ALLOCATIONS OF THE BSAI ATKA MACKEREL TAC

[Amounts are in metric tons]

Sector [1]	Season [2 3 4]	2016 Allocation by area		
		Eastern Aleutian district/ Bering Sea	Central Aleutian district [5]	Western Aleutian district
TAC	n/a	28,500	16,000	10,500
CDQ reserve	Total	3,050	1,712	1,124
	A	1,525	856	562
	Critical Habitat	n/a	514	337
	B	1,525	856	562
	Critical Habitat	n/a	514	337
ICA	Total	225	75	40
Jig [6]	Total	122	0	0
BSAI trawl limited access	Total	2,433	1,421	0
	A	1,217	711	0
	Critical Habitat	n/a	426	0
	B	1,217	711	0
	Critical Habitat	n/a	426	0
Amendment 80 sectors	Total	22,670	12,792	9,337
	A	11,335	6,396	4,668
	B	11,335	6,396	4,668
Alaska Groundfish Cooperative	Total [6]	12,808	7,609	5,741
	A	6,404	3,805	2,871
	Critical Habitat	n/a	2,283	1,722
	B	6,404	3,805	2,871
	Critical Habitat	n/a	2,283	1,722
Alaska Seafood Cooperative	Total [6]	9,862	5,183	3,596
	A	4,931	2,592	1,798
	Critical Habitat	n/a	1,555	1,079
	B	4,931	2,592	1,798
	Critical Habitat	n/a	1,555	1,079

[1] Section 679.20(a)(8)(ii) allocates the Atka mackerel TACs, after subtracting the CDQ reserves, jig gear allocation, and ICAs to the Amendment 80 and BSAI trawl limited access sectors. The allocation of the ITAC for Atka mackerel to the Amendment 80 and BSAI trawl limited access sectors is established in Table 33 to part 679 and § 679.91. The CDQ reserve is 10.7 percent of the TAC for use by CDQ participants (see §§ 679.20(b)(1)(ii)(C) and 679.31).

[2] Sections 679.20(a)(8)(ii)(A) and 679.22(a) establish temporal and spatial limitations for the Atka mackerel fishery.

[3] The seasonal allowances of Atka mackerel are 50 percent in the A season and 50 percent in the B season.

[4] Section 679.23(e)(3) authorizes directed fishing for Atka mackerel with trawl gear during the A season from January 20 to June 10 and the B season from June 10 to December 31.

[5] Section 679.20(a)(8)(ii)(C)(*1*)(*i*) limits no more than 60 percent of the annual TACs in Areas 542 and 543 to be caught inside of critical habitat; (a)(ii)(C)(*1*)(*ii*) equally divides the annual TACs between the A and B seasons as defined at § 679.23(e)(3); and (a)(8)(ii)(C)(*2*) requires the TAC in Area 543 shall be no more than 65 percent of ABC.

[6] Section 679.20(a)(8)(i) requires that up to 2 percent of the Eastern Aleutian District and the Bering Sea subarea TAC be allocated to jig gear after subtracting the CDQ reserve and ICA. The amount of this allocation is 0.5 percent. The jig gear allocation is not apportioned by season.

Note: Seasonal or sector apportionments may not total precisely due to rounding.

This will enhance the socioeconomic well-being of harvesters dependent upon Atka mackerel in this area. The Regional Administrator considered the following factors in reaching this decision: (1) The current catch of Atka mackerel ICA in the BS/EAI, (2) the harvest capacity and stated intent on future harvesting patterns of the Amendment 80 cooperatives that participate in this BS/EAI fishery.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of Atka mackerel from the BS/EAI ICA to the Amendment 80 cooperatives in the BSAI. Since the fishery is currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 30, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.91 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 3, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–24182 Filed 10–3–16; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE924

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is reallocating the projected unused amounts of Pacific cod from catcher vessels greater than 60 feet (18.3 meters (m)) length overall (LOA) using pot gear, catcher vessels using trawl gear, and vessels using jig gear to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear, catcher processors (C/Ps) using pot gear, and Amendment 80 (A80) C/Ps in the Bering Sea and Aleutian Islands management area. This action is necessary to allow the 2016 total allowable catch of Pacific cod to be harvested.

DATES: Effective October 5, 2016, through 2400 hours, Alaska local time (A.l.t.), December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands (BSAI) according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2016 Pacific cod TAC specified for catcher vessels greater than 60 feet (18.3 m) LOA using pot gear in the BSAI is 18,798 metric tons (mt) as established by the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773, March 18, 2016). The Regional Administrator has determined that catcher vessels greater than 60 feet (18.3 m) LOA using pot gear in the BSAI will not be able to harvest 1,200 mt of the remaining 2016 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*5*).

The 2016 Pacific cod TAC specified for catcher vessels using trawl gear in the BSAI is 49,638 mt as established by the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773, March 18, 2016). The Regional Administrator has determined that catcher vessels using trawl gear will not be able to harvest 1,000 mt of the remaining 2016 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*9*).

The 2016 Pacific cod TAC specified for vessels using jig gear in the BSAI is 394 mt as established by the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773, March 18, 2016) and reallocation (81 FR 57491, August 23, 2016). The Regional Administrator has determined that vessels using jig gear will not be able to harvest 300 mt of the remaining 2016 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*1*).

Therefore, in accordance with § 679.20(a)(7)(iii)(A) and § 679.20(a)(7)(iii)(B), NMFS reallocates 2,500 mt of Pacific cod to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear, C/Ps using pot gear, and A80 C/Ps in the Bering Sea and Aleutian Islands management area.

The harvest specifications for Pacific cod included in the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773, March 18, 2016, 81 FR 57491, August 23, 2016, 81 FR 61143, September 6, 2016) are revised as follows: 17,598 mt for catcher vessels greater than 60 feet (18.3 m) LOA using pot gear, 48,638 mt for catcher vessels using trawl gear, 94 mt for vessels using jig gear, 8,674 for catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear, 4,357 for C/Ps using pot gear, and 31,097 mt for A80 C/Ps.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of Pacific cod specified from multiple sectors to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear, C/Ps using pot gear, and A80 C/Ps in the Bering Sea and Aleutian Islands management area. Since these fisheries are currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 29, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 30, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–24116 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 81, No. 194

Thursday, October 6, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC–2004–0006, NRC–2002–0018]

RIN 3150–AH29

Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Rulemaking activity; discontinuation.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is discontinuing a rulemaking activity titled, ''Risk-Informed Changes to Loss-Of-Coolant Accident Technical Requirements.'' The purpose of this action is to inform members of the public of the discontinuation of this rulemaking and to provide a brief discussion of the NRC's decision to discontinue it. This rulemaking activity will no longer be reported in the NRC's portion of the Unified Agenda of Regulatory and Deregulatory Actions (the Unified Agenda).

DATES: Effective October 6, 2016, the rulemaking activity discussed in this document is discontinued.

ADDRESSES: Please refer to Docket ID NRC–2004–0006 for the rulemaking and Docket ID NRC–2002–0018 for the petition for rulemaking (PRM), PRM–50–75, when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2004–0006 for the rulemaking and Docket ID NRC–2002–0018 for PRM–50–75. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Robert Beall, Office of Nuclear Reactor Regulations, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3874; email: *Robert.Beall@nrc.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background
II. Process for Discontinuing Rulemaking Activities
III. Discussion
IV. Petition for Rulemaking (PRM–50–75)
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I. Background

In SECY–16–0009, ''Recommendations Resulting from the Integrated Prioritization and Re-Baselining of Agency Activities,'' dated January 31, 2016 (ADAMS Accession No. ML16028A189), the NRC staff requested Commission approval to implement recommendations on work to be shed, de-prioritized, or performed with fewer resources. One of the items listed to be shed (*i.e.,* discontinued) was a rulemaking titled, ''Risk-Informed Changes to Loss-Of-Coolant Accident Technical Requirements,'' that would have amended § 50.46 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Acceptance criteria for emergency core cooling systems (ECCS) for light-water nuclear power reactors'' (50.46a ECCS rulemaking). In the Staff Requirements Memorandum (SRM) for SECY–16–0009, dated April 13, 2016 (ADAMS Accession No. ML16104A158), the Commission approved discontinuing the 50.46a ECCS rulemaking, and directed the NRC staff to publish a **Federal Register** notice to inform the public that the rule is being discontinued.

A discussion of the NRC's decision to discontinue the rulemaking on ''Risk-Informed Changes to Loss-Of-Coolant Accident Technical Requirements'' is provided in Section III of this document.

II. Process for Discontinuing Rulemaking Activities

When the NRC staff identifies a rulemaking activity that can be discontinued, it will request, through a Commission paper, approval from the Commission to discontinue the rule. The Commission provides its decision by issuing an SRM. If the Commission approves discontinuing the rulemaking activity, the NRC staff will inform the public of the Commission's decision.

A rulemaking activity may be discontinued at any stage of the rulemaking process. For a rulemaking activity that has received public comments, the NRC staff will consider those comments before discontinuing it; however, the NRC staff will not provide individual comment responses.

After Commission approval to discontinue the rulemaking activity, the NRC staff will update the next edition of the Unified Agenda to indicate that the rulemaking is discontinued. The rulemaking activity will appear in the completed section of that edition of the Unified Agenda, but will not appear in subsequent editions.

III. Discussion

In the SRM for SECY–02–0057,[1] ''Update to SECY–01–0133, 'Fourth Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria),' '' dated March 31, 2003 (ADAMS Accession No.

[1] SECY–02–0057, ''Update to SECY–01–0133, 'Fourth Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria),' '' dated March 29, 2002 (ADAMS Accession No. ML020660607).

ML030910476), the Commission directed the NRC staff to prepare a proposed rule that would provide a risk-informed alternative maximum loss-of-coolant accident (LOCA) break size. On June 9, 2003, and July 24, 2003, the NRC staff held two public meetings [2] to obtain stakeholder feedback on this proposed rule. As a result of these interactions, the NRC staff found differences between the stated Commission objectives and industry stakeholder interests.

To reach a common understanding of the objectives of the rulemaking, the NRC staff requested additional Commission direction in SECY–04–0037, ''Issues Related to Proposed Rulemaking to Risk-Inform Requirements Related to Large Break Loss-of-Coolant Accident (LOCA) Break Size and Plans for Rulemaking on LOCA with Coincident Loss-of-Offsite Power,'' dated March 3, 2004 (ADAMS Accession No. ML040490133). The Commission directed the NRC staff in the SRM for SECY–04–0037, dated July 1, 2004 (ADAMS Accession No. ML041830412), to determine an appropriate risk-informed alternative break size and remove breaks larger than this size from the design-basis event category.

In SECY–05–0052, ''Proposed Rulemaking for 'Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements,' '' dated March 29, 2005 (ADAMS Accession No. ML050480172), the NRC staff provided a proposed rule to the Commission for approval. In the SRM for SECY–05–0052, dated July 29, 2005 (ADAMS Accession No. ML052100416), the Commission approved publication of the proposed rule.

On November 7, 2005, the NRC published the proposed rule in the **Federal Register** (70 FR 67597). After evaluating the public comments, the NRC staff completed the draft final rule language.

On October 31 and November 1, 2006, the NRC staff met with the Advisory Committee on Reactor Safeguards (ACRS) to discuss the draft final rule. In a letter dated November 16, 2006 (ADAMS Accession No. ML063190465), the ACRS recommended that the NRC staff not issue the rule in its current form and suggested numerous changes, primarily to strengthen the assurance of defense-in-depth provided for large pipe breaks.

The NRC staff evaluated the ACRS recommendations and, in SECY–07–0082, ''Rulemaking to Make Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements; 10 CFR 50.46a, 'Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light Water Nuclear Power Reactors,' '' dated May 16, 2007 (ADAMS Accession No. ML070180692), sought additional Commission direction on both the priority of the rule and the issues raised by the ACRS. In the SRM for SECY–07–0082, dated August 10, 2007 (ADAMS Accession No. ML072220595), the Commission approved the NRC staff's recommendations for a revised rule priority and an approach for addressing ACRS concerns and completing the final rule.

The NRC staff modified the rule by making numerous substantive changes in the draft final rule. The NRC published a supplemental proposed rule for public comment on August 10, 2009 (74 FR 40006). The NRC staff evaluated the public comments received on the supplemental proposed rule and prepared a revised draft final rule. The draft final rule language was made publicly available on May 12, 2010, in the rulemaking docket on *www.regulations.gov* (NRC–2004–0006). The NRC staff prepared the final draft rule and discussed it in meetings with the ACRS subcommittee and full committee on September 22 and October 7, 2010. The ACRS provided its views on the rule to the Commission in a letter dated October 20, 2010 (ADAMS Accession No. ML102850279).

In SECY–10–0161, ''Final Rule: Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements (10 CFR 50.46(a)) (RIN 3150–AH29),'' dated December 10, 2010 (ADAMS Accession No. ML102210460), the NRC staff submitted a final rulemaking package to the Commission for approval. The Commission's review of the final rule was suspended to address higher-priority issues associated with the March 2011 Fukushima Dai-ichi accident. On April 20, 2012, the NRC staff requested to withdraw the 50.46a ECCS final rule from Commission consideration so that the NRC staff could review the rule and ensure its compatibility with the ongoing regulatory framework activities under Recommendation 1 of the Fukushima Near-Term Task Force report (ADAMS Accession No. ML111861807). The Commission approved the NRC staff's request in the SRM for SECY–10–0161, dated April 26, 2012 (ADAMS Accession No. ML12117A121).

In SECY–16–0009, the NRC staff recommended that the 50.46a ECCS rulemaking be discontinued. Based on interactions with the nuclear industry, the NRC staff understood that there were concerns with the potential implementation burden of the rule. The NRC staff's Regulatory Analysis for the 50.46a ECCS final rule (ADAMS Accession No. ML103230250) discussed the comments submitted by the Boiling Water Reactor Owners Group which conveyed that it would be extremely difficult to evaluate the cost-benefit due to uncertainties about the true cost of adopting the 50.46a ECCS rule. Furthermore, at a public meeting on the Risk Management Regulatory Framework paper, certain industry representatives indicated that the industry would not be interested in implementing the final rule.

As explained in SECY–16–0009, this rule would be voluntary if issued, so licensees could choose to not implement the requirements. Therefore, the NRC staff believes that there is minimal adverse impact on the NRC's mission, principles, or values by discontinuing this rulemaking. In the SRM for SECY–16–0009, the Commission approved the NRC staff's recommendation to discontinue this rulemaking.

In summary, the NRC has decided not to proceed with this rulemaking activity because there is minimal adverse impact on our mission, principles, or values and the industry has indicated that there may not be much interest in implementing the final rule.

IV. Petition for Rulemaking (PRM–50–75)

On February 6, 2002, Anthony R. Pietrangelo, on behalf of the Nuclear Energy Institute (NEI), filed PRM–50–75 requesting that the NRC amend 10 CFR 50.46 to allow licensees to use an alternative to the double-ended guillotine break of the largest pipe in the reactor coolant system (ADAMS Accession No. ML020630082). On April 8, 2002 (67 FR 16654), the NRC published a notice of receipt and request for public comment for PRM–50–75. The comment period closed on June 24, 2002, and the NRC received 18 comment letters (ADAMS Accession No. ML082460625). The NRC staff determined that the issues raised in PRM–50–75 were appropriate for consideration and, in fact, the issues were already being considered in the 50.46a ECCS rulemaking. On November 6, 2008, the NRC published a **Federal Register** document (73 FR 66000) stating that the NRC would address the substantive comments filed in PRM–50–75 as part of the 50.46a ECCS rulemaking. In SECY–16–0009, the staff recommended discontinuing the 50.46a

[2] Meeting Summaries: June 9, 2003 (ADAMS Accession No. ML031810178), and July 24, 2003 (ADAMS Accession No. ML032130059).

ECCS rulemaking and stated that PRM–50–75 would be addressed by alternative means. The NRC will issue a separate **Federal Register** document to disposition PRM–50–75.

V. Conclusion

The NRC is no longer pursuing the ''Risk-Informed Changes to Loss-Of-Coolant Accident Technical Requirements'' rulemaking for the reasons discussed in this document. In the next edition of the Unified Agenda, the NRC will update the entry for this rulemaking and reference this document to indicate that the 50.46a ECCS rulemaking is no longer being pursued. This rulemaking activity will appear in the completed section of that edition of the Unified Agenda, but will not appear in subsequent editions. If the NRC decides to pursue a similar or related rulemaking in the future, it will inform the public through a new rulemaking entry in the Unified Agenda.

Dated at Rockville, Maryland, this 13th day of September 2016.

For the Nuclear Regulatory Commission.

Victor M. McCree,

Executive Director for Operations.

[FR Doc. 2016–24189 Filed 10–5–16; 8:45 am]

BILLING CODE 7590–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2016–0494; FRL–9953–65–Region 9]

Findings of Failure To Attain the 1997 $PM_{2.5}$ Standards; California; San Joaquin Valley

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to determine that the San Joaquin Valley nonattainment area failed to attain the 1997 annual and 24-hour fine particulate matter ($PM_{2.5}$) national ambient air quality standards by the December 31, 2015 ''Serious'' area attainment date. This proposed determination is based upon monitored air quality data from 2013 through 2015. If the EPA finalizes this determination as proposed, the State of California will be required to submit a revision to the California State Implementation Plan that, among other elements, provides for expeditious attainment of the 1997 $PM_{2.5}$ standards and for a five percent annual reduction in the emissions of direct $PM_{2.5}$ or a $PM_{2.5}$ plan precursor pollutant.

DATES: Any comments must arrive by November 7, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0494 at *http://www.regulations.gov,* or via email to Rory Mays at *mays.rory@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Rory Mays, Air Planning Office (AIR–2), EPA Region 9, (415) 972–3227, *mays.rory@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we'', ''us'' and ''our'' refer to the EPA.

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I. Background

A. $PM_{2.5}$ NAAQS

Under section 109 of the Clean Air Act (CAA or ''Act''), the EPA has established national ambient air quality standards (NAAQS or ''standards'') for certain pervasive air pollutants (referred to as ''criteria pollutants'') and conducts periodic reviews of the NAAQS to determine whether they should be revised or whether new NAAQS should be established.

On July 1, 1987 (52 FR 24634), the EPA replaced the original standard for particulate matter, measured as total suspended particulate matter (TSP) (*i.e.,* particles roughly 30 micrometers or less), with new standards that replaced TSP as the indicator for particulate matter with a new indicator that includes only those particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10}).

On July 18, 1997 (62 FR 38652), the EPA revised the standards for particulate matter by establishing new standards for particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers ($PM_{2.5}$). The EPA established primary and secondary annual and 24-hour standards for $PM_{2.5}$.[1] The annual primary and secondary standards were set at 15.0 micrograms per cubic meter ($\mu g/m^3$), based on a 3-year average of annual mean $PM_{2.5}$ concentrations, and the 24-hour primary and secondary standards were set at 65 $\mu g/m^3$, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each monitoring site within an area. See 40 CFR 50.7. Collectively, we refer herein to the 1997 24-hour and annual $PM_{2.5}$ NAAQS as the ''1997 $PM_{2.5}$ NAAQS'' or ''1997 $PM_{2.5}$ standards.''[2] The EPA

[1] For a given air pollutant, ''primary'' NAAQS are those determined by the EPA as requisite to protect the public health, allowing an adequate margin of safety, and ''secondary'' standards are those determined by the EPA as requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. See CAA section 109(b).

[2] On October 17, 2006 (71 FR 61144), the EPA revised the level of the 24-hour $PM_{2.5}$ standards to 35 $\mu g/m^3$, and on January 15, 2013 (78 FR 3086), the EPA revised the primary annual $PM_{2.5}$ standard to a level of 12.0 $\mu g/m^3$. We recently published a final rule revoking the 1997 primary annual $PM_{2.5}$ NAAQS for areas designated (or redesignated) attainment for that standard and revising the regulations governing implementation of the $PM_{2.5}$ standards. *See* 81 FR 58010 (August 24, 2016). However, because the San Joaquin Valley remains designated nonattainment for the 1997 annual primary $PM_{2.5}$ standard, the 1997 primary annual $PM_{2.5}$ standard will remain in effect in the San Joaquin Valley under the EPA's recent $PM_{2.5}$ implementation rule until such time as the area is redesignated to attainment for that standard. Thus, even though the EPA has lowered the 24-hour and

established these standards after considering substantial evidence from numerous health studies demonstrating that serious health effects are associated with exposures to $PM_{2.5}$ concentrations above these levels.

Epidemiological studies have shown statistically significant correlations between elevated $PM_{2.5}$ levels and premature mortality. Other important health effects associated with $PM_{2.5}$ exposure include aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions, emergency room visits, absences from school or work, and restricted activity days), changes in lung function and increased respiratory symptoms. There is also new evidence for more subtle indicators of cardiovascular health. Individuals particularly sensitive to $PM_{2.5}$ exposure include older adults, people with heart and lung disease, and children.[3]

$PM_{2.5}$ can be emitted directly into the atmosphere as a solid or liquid particle (primary $PM_{2.5}$ or direct $PM_{2.5}$) or can be formed in the atmosphere as a result of various chemical reactions from precursor emissions of nitrogen oxides, sulfur oxides, volatile organic compounds, and ammonia (secondary $PM_{2.5}$).[4]

B. San Joaquin Valley Designations, Classifications, and Attainment Dates for 1997 $PM_{2.5}$ NAAQS

Following promulgation of a new or revised NAAQS, the EPA is required under CAA section 107(d) to designate areas throughout the nation as attaining or not attaining the NAAQS. On January 5, 2005, the EPA published initial air quality designations for the 1997 annual and 24-hour $PM_{2.5}$ NAAQS, using air quality monitoring data for the three-year periods of 2001–2003 and 2002–2004.[5] These designations became effective April 5, 2005.[6] The EPA designated the San Joaquin Valley area as nonattainment for both the 1997 annual $PM_{2.5}$ standards and the 1997 24-hour $PM_{2.5}$ standards.[7]

The San Joaquin Valley $PM_{2.5}$ nonattainment area encompasses over 23,000 square miles and includes all or part of eight counties: San Joaquin, Stanislaus, Merced, Madera, Fresno, Tulare, Kings, and the valley portion of Kern.[8] The area is home to four million people and is the nation's leading agricultural region. Stretching over 250 miles from north to south and averaging 80 miles wide, it is partially enclosed by the Coast Mountain range to the west, the Tehachapi Mountains to the south, and the Sierra Nevada range to the east.

Under state law, the California Air Resources Board (CARB or ''State'') is the Governor's designee for adoption and submittal of the state implementation plan (SIP) and SIP revisions to the EPA in compliance with CAA requirements. CARB is also generally responsible under state law for the regulation of mobile emission sources. Local air pollution control districts are responsible for regulation of stationary emission sources. In the San Joaquin Valley, regional air quality plans are developed by the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD or ''District'') with input from CARB and typically rely on both mobile source control measures for which CARB is responsible and stationary source control measures for which the District is responsible. Once the District adopts a regional air quality plan, the plan is submitted to CARB for adoption as part of the California SIP and submittal to the EPA.

Between 2007 and 2011, California made six SIP submissions to address nonattainment area planning requirements for the 1997 $PM_{2.5}$ NAAQS in the San Joaquin Valley.[9] We refer to these submissions collectively as the ''2008 $PM_{2.5}$ Plan.'' On November 9, 2011, the EPA approved all elements of the 2008 $PM_{2.5}$ Plan except for the contingency measures, which the EPA disapproved.[10] As part of that action and pursuant to CAA section 172(a)(2)(A), the EPA granted California's request for an extension of the attainment date for the San Joaquin Valley area to April 5, 2015.[11]

A 2013 court decision by the U.S. Court of Appeals for the D.C. Circuit (''D.C. Circuit'') in *Natural Resources Defense Council* v. *EPA* concluded that the EPA erred in implementing the 1997 $PM_{2.5}$ standards solely pursuant to the general implementation requirements of subpart 1, without also considering the requirements specific to PM_{10} nonattainment areas in subpart 4, part D of title I of the CAA.[12] Consistent with the *NRDC* decision, on June 2, 2014, the EPA classified all areas designated nonattainment for the 1997 or the 2006 $PM_{2.5}$ standards as ''Moderate'' nonattainment areas under subpart 4.[13] Because this rulemaking did not affect any action that the EPA had previously taken under section 110(k) of the Act on a SIP for a $PM_{2.5}$ nonattainment area, the April 5, 2015 attainment date that the EPA had approved for the San Joaquin Valley area in November 2011 remained in effect.[14]

On April 7, 2015, the EPA reclassified the San Joaquin Valley area as a ''Serious'' $PM_{2.5}$ nonattainment area under subpart 4, based on the EPA's determination that the area could not practicably attain the 1997 $PM_{2.5}$ standards by the April 5, 2015 attainment date.[15] This reclassification was based upon the EPA's evaluation of ambient air quality data from the 2003–2014 period, including the 2012–2014 design value, which indicated that it was not practicable for certain monitoring sites within the San Joaquin Valley area to show $PM_{2.5}$ design values at or below the level of the 1997 $PM_{2.5}$ NAAQS by April 5, 2015.[16]

As a consequence of reclassification as a Serious $PM_{2.5}$ nonattainment area, the San Joaquin Valley area became subject to a new attainment date under CAA section 188(c)(2) and the requirement to submit a Serious area plan that satisfies the requirements of part D of title I of the Act, including the requirements of subpart 4, for the 1997 $PM_{2.5}$ NAAQS.[17] Under subpart 4, the attainment date for an area classified as Serious is as expeditiously as

annual $PM_{2.5}$ standards, the original 1997 $PM_{2.5}$ standards remain in effect in the San Joaquin Valley and represent the standards for which today's proposed determination are made.

[3] EPA, Air Quality Criteria for Particulate Matter, No. EPA/600/P–99/002aF and EPA/600/P–99/002bF, October 2004.

[4] 80 FR 15340, 15342 (March 23, 2015).

[5] 70 FR 944 (January 5, 2005).

[6] *Id.*

[7] 40 CFR 81.305. The 2001–2003 design values for the San Joaquin Valley were 21.8 μg/m³ for the annual standard and 82 μg/m³ for the 24-hour standard. *See* EPA design value workbook dated August 28, 2014, worksheets ''Table 3a'' and ''Table 3b.''

[8] For a precise description of the geographic boundaries of the San Joaquin Valley $PM_{2.5}$ nonattainment area, *see* 40 CFR 81.305.

[9] 76 FR 69896 at n. 2 (November 9, 2011).

[10] *Id.* at 69924.

[11] *Id.* Under CAA section 172(a)(2)(A), the attainment date for a nonattainment area is ''the date by which attainment can be achieved as expeditiously as practicable, but no later than five years from the date such area was designated nonattainment,'' except that EPA may extend the attainment date as appropriate for a period no greater than ten years from the date of designation as nonattainment, considering the severity of nonattainment and the availability and feasibility of pollution control measures. CAA section 172(a)(2)(A).

[12] *Natural Resources Defense Council* v. *EPA,* 706 F.3d 428 (D.C. Cir. 2013) (''*NRDC*'').

[13] 79 FR 31566 (June 2, 2014). As part of this rulemaking, EPA established a December 31, 2014 deadline for states to submit attainment-related and nonattainment new source review SIP elements required for $PM_{2.5}$ nonattainment areas pursuant to subpart 4. *Id.*

[14] *Id.* at 31569.

[15] 80 FR 18528 (April 7, 2015).

[16] *Id.* at 18529; *see also* proposed rule, 80 FR 1482 (January 12, 2015). Air quality data for 2012–2014 indicated that the highest monitors in the San Joaquin Valley area had design values of 19.7 μg/m³ for the annual standard and 71 μg/m³ for the 24-hour standard.

[17] 80 FR 18258 at 18530–18532.

practicable, but no later than the end of the tenth calendar year following designation. As explained in the EPA's final reclassification action, the Serious area plan for the San Joaquin Valley must include provisions to assure that the best available control measures for the control of direct $PM_{2.5}$ and $PM_{2.5}$ precursors shall be implemented no later than 4 years after the area is reclassified (CAA section 189(b)(1)(B)), and a demonstration (including air quality modeling) that the plan provides for attainment as expeditiously as practicable but no later than December 31, 2015, which is the latest permissible attainment date under CAA section 188(c)(2).[18]

Given the December 31, 2015 outermost attainment deadline for the San Joaquin Valley area under section 188(c)(2), the EPA noted its expectation that the State would adopt and submit a Serious area plan for the San Joaquin Valley well before the statutory SIP submission deadlines in CAA section 189(b)(2).[19] The EPA also noted that, in light of the available ambient air quality data and the short amount of time available before the December 31, 2015 attainment date, California could choose to submit a request for an extension of the Serious area attainment date pursuant to CAA section 188(e) simultaneously with its submission of a Serious area plan for the area.[20]

California submitted its 1997 $PM_{2.5}$ Serious area plan for the San Joaquin Valley in two submittals dated June 25, 2015 and August 13, 2015, including a request under section 188(e) to extend the attainment date for the 1997 24-hour $PM_{2.5}$ NAAQS by three years (to December 31, 2018) and to extend the attainment date for the 1997 annual $PM_{2.5}$ NAAQS by five years (to December 31, 2020). The EPA proposed to approve most of the San Joaquin Valley 1997 $PM_{2.5}$ Serious area plan, to conditionally approve the Plan's quantitative milestones, to disapprove the plan's contingency measures, and to grant the requested attainment date extensions.[21] We received adverse comments on our proposal on several aspects of the plan and its control measures. Upon further evaluation of the plan and after consideration of the comments, the EPA decided it could no longer support an action to extend the attainment date for the San Joaquin Valley Serious $PM_{2.5}$ nonattainment area for the 1997 $PM_{2.5}$ NAAQS.[22]

Since the EPA has not approved the requested attainment date extensions, the applicable attainment date remains December 31, 2015 for the San Joaquin Valley with respect to the 1997 $PM_{2.5}$ NAAQS. As discussed in section II of this proposed rule, the EPA must determine, based on air quality data as of the attainment date, whether an area attained the applicable NAAQS by its attainment date.

II. Proposed Determination and Consequences

A. Applicable Statutory and Regulatory Provisions

Sections 179(c)(1) and 188(b)(2) of the CAA require the EPA to determine whether a $PM_{2.5}$ nonattainment area attained the applicable $PM_{2.5}$ standards by the applicable attainment date, based on the area's air quality as of the attainment date.

A determination of whether an area's air quality meets the $PM_{2.5}$ standards is generally based upon the most recent three years of complete, quality-assured data gathered at established State and Local Air Monitoring Stations (SLAMS) in a nonattainment area and entered into the EPA's Air Quality System (AQS) database. Data from ambient air monitors operated by state/local agencies in compliance with the EPA monitoring requirements must be submitted to AQS. Monitoring agencies annually certify that these data are accurate to the best of their knowledge. Accordingly, the EPA relies primarily on data in AQS when determining the attainment status of areas. *See* 40 CFR 50.7; 40 CFR part 50, Appendix L; 40 CFR part 53; 40 CFR part 58, and 40 CFR part 58, Appendices A, C, D, and E. All data are reviewed to determine the area's air quality status in accordance with 40 CFR part 50, Appendix N.

Under EPA regulations in 40 CFR part 50, § 50.7 and in accordance with Appendix N, the 1997 annual $PM_{2.5}$ standards are met when the design value is less than or equal to 15.0 μg/m³ (based on the rounding convention in 40 CFR part 50, Appendix N) at each eligible monitoring site within the area.[23] Data completeness requirements for a given year are met when at least 75 percent of the scheduled sampling days for each quarter have valid data.

Under EPA regulations in 40 CFR part 50, section 50.7 and in accordance with Appendix N, the 1997 24-hour $PM_{2.5}$ standards are met when the design value is less than or equal to 65 μg/m³ (based on the rounding convention in 40 CFR part 50, Appendix N) at each eligible monitoring site within the area.[24] Data completeness requirements for a given year are met when at least 75 percent of the scheduled sampling days for each quarter have valid data.

B. Monitoring Network Considerations

Section 110(a)(2)(B)(i) of the CAA requires states to establish and operate air monitoring networks to compile data on ambient air quality for all criteria pollutants. Our monitoring requirements are specified by regulation in 40 CFR part 58. These requirements are applicable to state, and where delegated, local air monitoring agencies that operate criteria pollutant monitors. Our regulations in 40 CFR part 58 establish specific requirements for operating air quality surveillance networks to measure ambient concentrations of $PM_{2.5}$, including requirements for measurement methods, network design, quality assurance procedures, and in the case of large urban areas, the minimum number of monitoring sites designated as SLAMS.

In section 4.7 of Appendix D to 40 CFR part 58, the EPA specifies minimum monitoring requirements for $PM_{2.5}$ to operate at SLAMS. SLAMS produce data that are eligible for comparison with the NAAQS, and therefore, the monitor must be an approved federal reference method (FRM), federal equivalent method (FEM), or approved regional method (ARM). The minimum number of SLAMS required is described in section 4.7.1, and can be met by either filter-based or continuous FRMs or FEMs. The monitoring regulations also provide that each core-based statistical area must operate a minimum number of $PM_{2.5}$ continuous monitors (section 4.7.2); however, this requirement can be met by either an FEM or a non-FEM continuous monitor, and the continuous monitors can be located with other SLAMS or at a different location.

[18] *Id.*

[19] *Id.* at 18531.

[20] *Id.*

[21] 81 FR 6936 (February 9, 2016).

[22] *See* U.S. EPA, Final rule, ''Denial of Request for Extension of Attainment Date for 1997 $PM_{2.5}$ NAAQS; California; San Joaquin Valley Serious Nonattainment Area,'' to be published in the same edition of the **Federal Register** as this proposed rule, and U.S. EPA Fact Sheet, ''San Joaquin Valley Fine Particulate Matter,'' June 29, 2016.

[23] The annual $PM_{2.5}$ standard design value is the 3-year average of annual mean concentration, and the 1997 annual $PM_{2.5}$ NAAQS are met when the annual standard design value at each eligible monitoring site is less than or equal to 15.0 μg/m³.

[24] The 24-hour $PM_{2.5}$ standard design value is the 3-year average of annual 98th percentile 24-hour average values recorded at each eligible monitoring site, and the 1997 24-hour $PM_{2.5}$ NAAQS are met when the 24-hour standard design value at each such monitoring site is less than or equal to 65 μg/m³.

Consequently, the monitoring requirements for $PM_{2.5}$ can be met with filter-based FRMs/FEMs, continuous FEMs, continuous non-FEMs, or a combination of monitors at each required SLAMS.

Under 40 CFR 58.10, states are required to submit Annual Network Plans for ambient air monitoring networks for approval by the EPA. Within the San Joaquin Valley, CARB and the District are the agencies responsible for assuring that the area meets air quality monitoring requirements. The District submits annual monitoring network plans to the EPA that describe the various monitoring sites operated by the District as well as those operated by CARB within the San Joaquin Valley. These plans discuss the status of the air monitoring network, as required under 40 CFR 58.10. The most recent plan submitted by the District is the 2015 Air Monitoring Network Plan, dated August 28, 2015. The EPA regularly reviews these Annual Network Plans for compliance with the applicable reporting requirements in 40 CFR part 58. On December 28, 2015, the EPA approved those portions of the 2015 Air Monitoring Network Plan that pertain to the adequacy of the network for $PM_{2.5}$ monitoring purposes.[25]

During the 2013–2015 period, $PM_{2.5}$ ambient concentration data that is eligible for use in determining whether an area has attained the $PM_{2.5}$ NAAQS were collected at a total of 17 sites within the San Joaquin Valley: four sites in Fresno County; three sites in Kern County; two sites each in Kings, Merced, San Joaquin, and Stanislaus counties; and one site each in Madera and Tulare counties. The District operates 10 of these sites while CARB operates seven of the sites. Fourteen of the sites are designated SLAMS for $PM_{2.5}$. Three of the sites are designated as special purpose monitors (*i.e.,* the Merced (Coffee Street), Tranquility, and Hanford sites), but the $PM_{2.5}$ data collected there are eligible for use in determining $PM_{2.5}$ NAAQS compliance due to the duration of monitoring at the site and the use of FRM or FEM monitors consistent with EPA quality assurance requirements and siting criteria.[26] The primary monitors are FRMs at 11 of the 17 sites and beta attenuation monitor FEMs at six of the 17 sites.

Based on our review of the $PM_{2.5}$ monitoring network as summarized above, we find that monitoring network in the San Joaquin Valley is adequate for the purpose of collecting ambient $PM_{2.5}$ concentration data for use in determining whether the San Joaquin Valley attained the 1997 $PM_{2.5}$ NAAQS by the December 31, 2015 attainment date.

C. Data Considerations and Proposed Determination

Under 40 CFR 58.15, monitoring agencies must certify, on an annual basis, data collected at all SLAMS and at all FRM, FEM, and ARM SPM stations that meet EPA quality assurance requirements. In doing so, monitoring agencies must certify that the previous year of ambient concentration and quality assurance data are completely submitted to AQS and that the ambient concentration data are accurate to the best of her or his knowledge. CARB annually certifies that the data the agency submits to AQS are quality assured, including data collected by CARB at monitoring sites in the San Joaquin Valley.[27] SJVUAPCD does the same for data submitted to AQS from monitoring sites operated by the District.[28]

As noted above, CAA sections 179(c)(1) and 188(b)(2) require the EPA to determine whether a $PM_{2.5}$ nonattainment area attained the applicable $PM_{2.5}$ standards by the applicable attainment date, based on the area's air quality ''as of the attainment date.'' For the San Joaquin Valley, for reasons discussed above, the applicable attainment date is December 31, 2015 with respect to the 1997 $PM_{2.5}$ NAAQS. Because determinations of $PM_{2.5}$ NAAQS compliance, in accordance with 40 CFR part 50, Appendix N, are based on three calendar years of data, to determine the San Joaquin Valley's air quality as of December 31, 2015, we must review the data collected during the three-year period immediately preceding December 31, 2015, *i.e.,* January 1, 2013–December 31, 2015.

Thus, we verified that the data for the 2013–2015 period have been certified by the relevant monitoring agencies, and then we reviewed the data for completeness. We note above the most recent annual data certifications from CARB and the District. With respect to completeness, we determined that the data collected by CARB and the District meet the quarterly completeness criterion for all 12 quarters of the three-year period at most of the $PM_{2.5}$ monitoring sites in the San Joaquin Valley.

More specifically, among the 17 $PM_{2.5}$ monitoring sites from which regulatory data are available, the data from four of the sites did not meet the 75% completeness criterion (for each quarter); however, the data from all but one site (Bakersfield—Golden State Highway) are sufficient nonetheless to produce a valid design value for either the annual $PM_{2.5}$ NAAQS or the 24-hour $PM_{2.5}$ NAAQS pursuant to the rules governing design value validity in 40 CFR part 50, Appendix N, sections 4.1 and 4.2. We note that monitors with incomplete data in one or more quarters may still produce valid design values if the conditions for applying one of the EPA's data substitution tests are met.[29]

Table 1 and Table 2 show the annual and 24-hour $PM_{2.5}$ design values, respectively, at each of the 17 monitoring sites within the San Joaquin Valley nonattainment area for the relevant three-year period (2013–2015). The tables show that the annual $PM_{2.5}$ design values for the 2013–2015 period are greater than 15.0 μg/m³ at eight of the sites and that the 24-hour $PM_{2.5}$ design values are greater than 65 μg/m³ at four of the sites.

[25] Letter dated December 28, 2015, from Meredith Kurpius, Manager, EPA Region 9, Air Quality Analysis Office, to Sheraz Gill, Director of Strategies and Incentives, SJVUAPCD.

[26] There are a number of other $PM_{2.5}$ monitoring sites within the valley, including other sites operated by the District, the National Park Service, and certain Indian tribes, but the data collected from these sites are non-regulatory and not eligible for use in determining whether the San Joaquin Valley has attained the $PM_{2.5}$ NAAQS.

[27] *See, e.g.,* letter from Ravi Ramalingam, Chief, Consumer Products and Air Quality Assessment Branch, CARB, to Elizabeth Adams, Acting Director, Air Division, EPA Region 9, certifying calendar year 2015 ambient air quality data and quality assurance data, dated May 10, 2016.

[28] *See, e.g.,* letter from Jon Klassen, Program Manager, SJVUAPCD, letter to Deborah Jordan, Director, Air Division, EPA Region 9, certifying calendar year 2015 ambient air quality data and quality assurance data, dated May 9, 2016.

[29] *See* 40 CFR part 50, Appendix N, section 4.1(b) for the annual $PM_{2.5}$ NAAQS and section 4.2(b) for the 24-hour $PM_{2.5}$ NAAQS. Each year the EPA produces a workbook identifying $PM_{2.5}$ monitors with valid design values taking into account the data substitution tests set forth in 40 CFR part 50, Appendix N, section 4 where appropriate. The workbook design values reflect the concentration data input to AQS, but the design values calculated therein differ for some monitors from the design values calculated by AQS because at this time only the workbook design values accurately accounts for the two data substitution tests set forth in 40 CFR part 50, Appendix N, section 4.0.

TABLE 1—2013–2015 ANNUAL $PM_{2.5}$ DESIGN VALUES FOR THE SAN JOAQUIN VALLEY NONATTAINMENT AREA

General location	Site (AQS ID)	Annual Mean (μg/m³)			2013–2015 Annual design values (μg/m³)
		2013	2014	2015	
Fresno County:					
Fresno–Pacific	06–019–5025	15.9	13.8	14.1	14.6
Fresno—Garland	06–019–0011	16.8	15.1	14.4	15.4
Clovis	06–019–5001	15.9	14.8	15.0	15.2
Tranquility [a]	06–019–2009	8.3	Inc	10.0	8.7
Kern County:					
Bakersfield—Planz Road	06–029–0016	22.8	21.6	17.9	20.8
Bakersfield—California Ave.	06–029–0014	20.0	18.6	16.3	18.3
Bakersfield—Golden State Highway	06–029–0010	Inc	Inc	16.7	Inv
Kings County:					
Corcoran [a b]	06–031–0004	15.6	15.4	Inc	22.2
Hanford	06–031–1004	18.2	17.5	16.6	17.4
Madera County:					
Madera—Avenue 14	06–039–2010	17.8	14.0	13.8	15.2
Merced County:					
Merced—M Street	06–047–2510	13.5	11.2	12.6	12.5
Merced—Coffee	06–047–0003	13.3	10.8	12.8	12.3
San Joaquin County:					
Stockton	06–077–1002	17.7	12.1	12.8	14.2
Manteca	06–077–2010	11.7	9.8	12.6	11.4
Stanislaus County:					
Modesto	06–099–0005	14.5	11.4	Inc	Inv
Turlock	06–099–0006	15.1	12.3	14.4	13.9
Tulare County:					
Visalia	06–107–2002	18.9	17.9	16.1	17.6

Notes: Inc = Incomplete data. Inv = Invalid design value due to incomplete data. Design values shown in bold type do not meet the applicable NAAQS.

Source: EPA, AQS Design Value Report, Report Request ID: 1463864, July 15, 2016, except as otherwise noted.

[a] Source: EPA, design value workbook dated July 29, 2016, worksheet "Table 5. $PM_{2.5}$ Site Listing, 2013–2015," column S.

[b] The 2015 design value site (Corcoran-Patterson) is based on concentration data from January 1, 2013 to February 6, 2015. Data from February 7, 2015 to December 31, 2015 are not available due to a fire that destroyed the site. Based on design value calculation methodologies described in 40 CFR part 50, Appendix N, section 4.1(b), the annual design value for Corcoran-Patterson is considered valid despite the missing 2015 data. The second highest 2013–2015 concentration (annual $PM_{2.5}$ design value of 20.8 μg/m³) at Bakersfield-Planz includes data measured for three years (January 1, 2013–December 31, 2015).

TABLE 2—2013–2015 24-HOUR $PM_{2.5}$ DESIGN VALUES FOR THE SAN JOAQUIN VALLEY NONATTAINMENT AREA

General location	Site (AQS ID)	98th Percentile (μg/m³)			2013–2015 24-Hour design values (μg/m³)
		2013	2014	2015	
Fresno County:					
Fresno—Pacific	06–019—5025	71.6	61.8	42.0	58
Fresno–Garland	06–019–0011	63.8	66.7	52.0	61
Clovis	06–019–5001	56.2	64.5	45.7	55
Tranquility [a]	06–019–2009	35.7	Inc	35.8	34
Kern County:					
Bakersfield—Planz Road	06–029–0016	96.7	76.7	56.5	**77**
Bakersfield—California Ave.	06–029–0014	71.8	79.9	57.2	**70**
Bakersfield—Golden State Highway [a]	06–029–0010	Inc	107.2	51.5	Inv
Kings County:					
Corcoran [b]	06–031–0004	66.0	71.0	99.2	**79**
Hanford	06–031–1004	67.6	81.9	51.4	**67**
Madera County:					
Madera—Avenue 14	06–039–2010	54.6	56.0	43.7	51
Merced County:					
Merced—M Street	06–047–2510	67.3	45.9	39.0	51
Merced—Coffee	06–047–0003	42.3	43.8	40.3	42
San Joaquin County:					
Manteca	06–077–2010	40.2	40.0	42.7	41
Stockton	06–077–1002	56.3	44.5	39.1	47
Stanislaus County:					
Modesto	06–099–0005	56.4	49.5	30.8	46
Turlock	06–099–0006	55.4	51.2	47.3	51
Tulare County:					

TABLE 2—2013–2015 24-HOUR $PM_{2.5}$ DESIGN VALUES FOR THE SAN JOAQUIN VALLEY NONATTAINMENT AREA—Continued

General location	Site (AQS ID)	98th Percentile (μg/m³)			2013–2015 24-Hour design values (μg/m³)
		2013	2014	2015	
Visalia	06–107–2002	62.5	75.4	45.8	61

Notes: Inc = Incomplete data. Inv = Invalid design value due to incomplete data. Design values shown in bold type do not meet the applicable NAAQS.

Source: EPA, AQS Design Value Report, Report Request ID: 1463864, July 15, 2016, except as otherwise noted.

[a] Source: EPA, design value workbook dated July 29, 2016, worksheet "Table 5. $PM_{2.5}$ Site Listing, 2013–2015," column Z.

[b] The 2015 design value site (Corcoran-Patterson) is based on concentration data from January 1, 2013 to February 6, 2015. Data from February 7, 2015 to December 31, 2015 are not available due to a fire that destroyed the site. Based on design value calculation methodologies described in 40 CFR part 50, Appendix N, section 4.2(b), the 24-hour design value for Corcoran-Patterson is considered valid despite the missing 2015 data. The second highest 2013–2015 concentration (24-hour $PM_{2.5}$ design value of 77 μg/m³) at Bakersfield—Planz includes data measured for three years (January 1, 2013–December 31, 2015).

The data in Tables 1 and 2 show that a number of sites in central and southern San Joaquin Valley failed to attain the 1997 annual $PM_{2.5}$ NAAQS by December 31, 2015 and that the geographic extent of failure to attain the 1997 24-hour $PM_{2.5}$ NAAQS was more limited than for the annual standard in that only sites in southwestern San Joaquin Valley failed to attain the 24-hour standard. The 2015 annual design value site, *i.e.,* the site with the highest design value based on 2013–2015 data, is the Corcoran site with a 2015 annual $PM_{2.5}$ design value of 22.2 μg/m³. With respect to the 24-hour average, the 2015 design value site is the Corcoran site with a 24-hour $PM_{2.5}$ design value of 79 μg/m³.

For an area to attain the 1997 $PM_{2.5}$ NAAQS by December 31, 2015, the 2015 design value (reflecting data from 2013–2015) at each eligible monitoring site must be equal to or less than 15.0 μg/m³ for the annual standard and 65 μg/m³ for the 24-hour standard. Tables 1 and 2 show that the 2015 design values at a number of sites in the San Joaquin Valley are greater than those values. Therefore, based on quality-assured and certified data for 2013–2015, we are proposing to determine that the San Joaquin Valley failed to attain the 1997 annual and 24-hour $PM_{2.5}$ standards by the December 31, 2015 attainment date.

Lastly, we note that, under our regulations at 40 CFR 50.14, a monitoring agency may request the EPA to exclude data showing exceedances or violations of the standard that are directly due to an exceptional event from use in determinations by demonstrating that such event caused a specific air pollution concentration at a particular air quality monitoring location. A monitoring agency notifies the EPA of its intent to request exclusion of concentrations by placing a "flag" in the appropriate field for the data of concern in AQS.

For $PM_{2.5}$ ambient data collected from 2013–2015, the District "flagged" one 24-hour concentration at the Bakersfield (Planz Road) site and two 24-hour concentrations at the Bakersfield (California Avenue) site due to high winds. The District also flagged twenty-four 24-hour concentrations at each of the Madera and Merced (Coffee Avenue) sites due to wildfire.[30]

The State has not requested concurrence on the flagged data, and thus the data are not excluded from the set of data used to determine whether the standard was attained. However, even if all of the flagged data were to be excluded, *i.e.,* even if the EPA had concurred on the data as qualifying as exceptional events, the design values reported in Tables 1 and 2, though slightly lower at certain sites, would remain well above the NAAQS.[31]

For instance, the 2015 annual $PM_{2.5}$ design value at the Bakersfield (Planz Road) monitoring site would be 20.4 μg/m³ instead of 20.8 μg/m³ if all of the flagged data were excluded. Thus, it would still fail to attain the applicable standard of 15.0 μg/m³. Similarly, the 2015 24-hour $PM_{2.5}$ design value at the same site would be 72 μg/m³ instead of 77 μg/m³ if all of the flagged data were excluded, thus also failing to attain the applicable standard of 65 μg/m³. Furthermore, several additional sites, for which the District has not flagged exceptional events, exceed the 1997 $PM_{2.5}$ NAAQS based on 2015 annual $PM_{2.5}$ design values (*i.e.,* Fresno-Garland, Clovis, Corcoran, Hanford, and Visalia) and 2015 24-hour design values (*i.e.,* Corcoran and Hanford).

D. Consequences for Serious $PM_{2.5}$ Nonattainment Area Failing To Attain Standards by Attainment Date

The consequences for a Serious $PM_{2.5}$ nonattainment area for failing to attain the standards by the applicable attainment date are set forth in CAA sections 179(d) and 189(d). Under section 179(d), a state must submit a SIP revision for the area meeting the requirements of CAA section 110 and 172, the latter of which requires, among other elements, a demonstration of attainment and reasonable further progress, and contingency measures. CAA section 189(d) requires that the SIP revision must provide for attainment of the standards and, from the date of the SIP submittal until attainment, for an annual reduction in the emissions of $PM_{2.5}$ or a $PM_{2.5}$ plan precursor pollutant within the area of not less than five percent of the amount of such emissions as reported in the most recent inventory prepared for such area.[32] The requirement for a new attainment demonstration under CAA section 189(d) also triggers the requirement for the SIP revision for quantitative milestones under section 189(c) that are to be achieved every three years until redesignation to attainment.

The new attainment date is set by CAA section 179(d)(3), which relies upon section 172(a)(2) to establish a new attainment date but with a different starting point than provided in section 172(a)(2). Under section 179(d)(3), the new attainment date is the date by which attainment can be achieved as expeditiously as practicable, but no later than five years from the date of the final determination of failure to attain, except that the EPA may extend the attainment

[30] EPA, AQS Raw Data Qualifier Report, Report Request ED: 1464417, July 18, 2016.

[31] EPA, AQS Design Value Report, Report Request ED: 1463865, July 15, 2016.

[32] 81 FR 58010 at 58100, 58158 (August 24, 2016). The EPA defines $PM_{2.5}$ plan precursor as those $PM_{2.5}$ precursors required to be regulated in the applicable attainment plan and/or nonattainment new source review program. 81 FR 58010 at 58152.

date for a period no greater than 10 years from the final determination, considering the severity of nonattainment and the availability and feasibility of pollution control measures. Lastly, section 179(d) requires that the state submit the required SIP revision within 12 months after the applicable attainment date. In this case, if the EPA finalizes the proposed rule, then the State of California will be required to submit a SIP revision that complies with sections 179(d) and 189(d) within 12 months of December 31, 2015, *i.e.,* by December 31, 2016.

III. Proposed Action and Request for Public Comment

Under CAA sections 179(c)(1) and 188(b)(2), the EPA proposes to determine that the San Joaquin Valley ''Serious'' $PM_{2.5}$ nonattainment area has failed to attain the 1997 annual and 24-hour $PM_{2.5}$ standards by the applicable attainment date of December 31, 2015. If finalized, the State of California will be required under CAA sections 179(d) and 189(d) to submit a revision to the SIP for the San Joaquin Valley that, among other elements, demonstrates expeditious attainment of the standards within the time period provided under CAA section 179(d) and that provides for annual reduction in the emissions of $PM_{2.5}$ or a $PM_{2.5}$ plan precursor pollutant within the area of not less than five percent until attainment. The SIP revision required under CAA sections 179(d) and 189(d) would be due for submittal to the EPA no later than December 31, 2016.

The EPA is soliciting public comments on the issues discussed in this document. We will accept comments from the public on this proposal for the next 30 days. We will consider these comments before taking final action.

IV. Statutory and Executive Order Reviews

This proposed action in and of itself establishes no new requirements; it merely documents that air quality in the San Joaquin Valley did not meet the 1997 $PM_{2.5}$ standards by the CAA deadline. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed action does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP obligations discussed herein do not apply to Indian Tribes and thus this proposed action will not impose substantial direct costs on Tribal governments or preempt Tribal law. Nonetheless, the EPA has notified the Tribes within the San Joaquin Valley $PM_{2.5}$ nonattainment area of the proposed action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ammonia, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: September 23, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

[FR Doc. 2016–24084 Filed 10–5–16; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2016–0121; 4500030113]

RIN 1018–BB46

Endangered and Threatened Wildlife and Plants; Threatened Species Status for Louisiana Pinesnake

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Louisiana pinesnake (*Pituophis ruthveni*), a reptile species from Louisiana and Texas, as a threatened species under the Endangered Species Act (Act). If we finalize this rule as proposed, it would extend the Act's protections to this species.

DATES: We will accept comments received or postmarked on or before December 5, 2016. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by November 21, 2016.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R4–ES–2016–0121, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R4–ES–2016–0121, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

FOR FURTHER INFORMATION CONTACT: Brad S. Rieck, Acting Field Supervisor, U.S. Fish and Wildlife Service, Louisiana

Ecological Services Office, 646 Cajundome Blvd., Suite 400, Lafayette, LA; telephone 337–291–3101; facsimile 337–291–3139. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if we determine that a species is an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposed rule in the **Federal Register** and make a determination on our proposal within 1 year. Critical habitat shall be designated, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designations of critical habitat can only be completed by issuing a rule. We have determined that designating critical habitat for the Louisiana pinesnake is prudent, but not determinable at this time, because the specific information sufficient to perform the required analysis of the impacts of the designation is currently lacking, such as information on areas to be proposed for designation and the potential economic impacts associated with designation of these areas.

This rule proposes to list the Louisiana pinesnake as a threatened species. The Louisiana pinesnake is a candidate species for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing rule had been, until now, precluded by other higher priority listing activities.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the Louisiana pinesnake is threatened primarily because of the past and continuing loss, degradation, and fragmentation of habitat in association with incompatible silviculture, fire suppression, road and right-of-way construction, and urbanization (Factor A), and the magnified vulnerability of all the small, isolated, genetically compromised extant populations to mortality from vehicle strikes and from predators (Factors C and E).

We will seek peer review. We will seek comments from independent specialists to ensure that our designation is based on scientifically sound data, assumptions, and analyses. We will invite these peer reviewers to comment on this listing proposal.

Information Requested

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The Louisiana pinesnake's biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

(5) Information on activities that might warrant being exempted under section 4(d) of the Act (16 U.S.C. 1531 *et seq.*). The Service is considering proposing such measures before the final listing determination is published, and will evaluate ideas provided by the public in considering whether such exemptions are necessary and advisable for the conservation of the Louisiana pinesnake.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Louisiana Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Because we will consider all comments and information we receive during the comment period, our final determination may differ from this proposal.

Public Hearing

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we are seeking the expert opinions of six appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our listing determination is based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise in Louisiana pinesnake biology, habitat, physical or biological factors, etc., and they are currently reviewing the status information in the proposed rule, which will inform our determination. We invite comment from the peer reviewers during this public comment period.

Previous Federal Actions

We identified the Louisiana pinesnake (as *Pituophis melanoleucus ruthveni*) as a Category 2 candidate species in the December 30, 1982, Review of Vertebrate Wildlife for Listing as Endangered or Threatened Species (47 FR 58454). Category 2 candidates were defined as taxa for which we had information that proposed listing was possibly appropriate, but for which substantial data on biological vulnerability and threats were not available to support a proposed rule at the time. The species remained so designated in subsequent annual candidate notices of review (CNORs) (50 FR 37958, September 18, 1985; 54 FR 554, January 6, 1989; 56 FR 58804, November 21, 1991; 59 FR 58982, November 15, 1994). In the February 28, 1996, CNOR (61 FR 7596), we discontinued the designation of Category 2 species as candidates; therefore, the Louisiana pinesnake was no longer a candidate species.

We added the Louisiana pinesnake (as *Pituophis melanoleucus*) to the candidate list in 1999 (64 FR 57534, October 25, 1999). Currently, candidate species are defined as plants and animals for which the Service has sufficient information on their biological status and threats to propose them as endangered or threatened under the Act, but for which development of a listing rule is precluded by other higher priority listing actions. The Louisiana pinesnake was assigned a listing priority number (LPN) of 5, based on the immediacy and magnitude of threats to this species.

In the October 30, 2001, CNOR (66 FR 54808), we recognized the Louisiana pinesnake as *Pituophis ruthveni* and retained an LPN of 5 for the species. The Louisiana pinesnake was included with an LPN of 5 in our subsequent annual CNORs through 2005 (67 FR 40657, June 13, 2002; 69 FR 24876, May 4, 2004; 70 FR 24870, May 11, 2005). In 2006, we changed the Louisiana pinesnake's LPN to 8, based on threats of moderate to low magnitude that were imminent (71 FR 53756; September 12, 2006). In 2007, we again changed the Louisiana pinesnake's LPN, reassigning it an LPN of 5, based on non-imminent, high-magnitude threats (72 FR 69034; December 6, 2007). The Louisiana pinesnake was included with an LPN of 5 in our subsequent annual CNORs through 2015 (73 FR 75176, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; 80 FR 80584, December 24, 2015).

In August 2000, the Service received a petition to list the Louisiana pinesnake as endangered under the Act. No new information was provided in the petition, and we had already found the species warranted listing, so no further action was taken on the petition.

On May 10, 2011, the Service announced a work plan to restore biological priorities and certainty to the Service's listing process. As part of an agreement with one of the agency's most frequent plaintiffs, the Service filed the work plan with the U.S. District Court for the District of Columbia. The work plan enabled the Service to, over a period of 6 years, systematically review and address the needs of more than 250 species listed within the 2010 CNOR, including the Louisiana pinesnake, to determine if these species should be added to the Federal Lists of Endangered and Threatened Wildlife and Plants. This work plan enabled the Service to again prioritize its workload based on the needs of candidate species, while also providing State wildlife agencies, stakeholders, and other partners with clarity and certainty about when listing determinations will be made. On July 12, 2011, the Service reached an agreement with another frequent plaintiff group and further strengthened the work plan, which allowed the agency to focus its resources on the species most in need of protection under the Act. These agreements were approved on September 9, 2011. Therefore, the timing of this proposed listing is, in part, an outcome of the work plan.

Background

Species Description and Taxonomy

Pinesnakes (genus *Pituophis*) are large, short-tailed, non-venomous, powerful constricting snakes with keeled scales, a single anal plate (the scale covering the cloaca), and disproportionately small heads (Conant and Collins 1991, pp. 201–202). Their snouts are pointed, and they have a large rostral (tip of the snout) scale, both presumably contributing to the snakes good burrowing ability. The Louisiana pinesnake (*P. ruthveni*) has a buff to yellowish background color with dark brown to russet dorsal blotches covering its total length (Vandeventer and Young 1989, p. 35; Conant and Collins 1991, p. 203). The belly of the Louisiana pinesnake is unmarked or boldly patterned with black markings. It is variable in both coloration and pattern, but a characteristic feature is that the body markings on its back are always conspicuously different at opposite ends of its body. Blotches run together near the head, often obscuring the background color, and then become more separate and well-defined towards the tail. Typically, there are no noticeable head markings, although rarely a light bar or stripe may occur behind the eye. The length of adult Louisiana pinesnakes ranges from 48 to 56 inches (in) (122 to 142 centimeters (cm)) (Conant and Collins 1991, p. 203). The largest reported specimen was 5.8 feet (ft) (178 cm) long (Davis 1971, p. 1; Conant and Collins 1991, p. 203).

The Louisiana pinesnake is a member of the Class Reptilia, Order Squamata, Suborder Serpentes, and Family Colubridae. Stull (1929, pp. 2–3) formally described the Louisiana pinesnake as a pinesnake subspecies (*P. melanoleucus ruthveni*) based on two specimens taken in Rapides Parish, Louisiana. Reichling (1995, p. 192) reassessed this snake's taxonomic status and concluded that the Louisiana pinesnake was geographically isolated and phenotypically distinct, and thus a valid evolutionary species. The Louisiana pinesnake has subsequently been accepted as a full species, *P. ruthveni* (Crother 2000, p. 69; Rodriguez-Robles and Jesus-Escobar 2000, p. 46; Collins and Taggert 2002, p. 33). We have carefully reviewed this taxonomic research for the Louisiana pinesnake and conclude that the species is a valid taxon.

Habitat

Louisiana pinesnakes are known from and associated with a disjunct portion of the historic longleaf-dominated (hereafter, ''longleaf'') pine (*Pinus palustris*) ecosystem that existed in west-central Louisiana and east Texas (Reichling 1995, p. 186). Longleaf pine forests (which are dominated by longleaf, but may also contain other

overstory species such as loblolly and shortleaf pine and sparse hardwoods) have the most species-rich herpetofaunal community compared to other similarly sized and located pine forest habitat in North America, and harbor more species that are specialists of that habitat (Guyer and Bailey 1993, p. 142). Early accounts of Louisiana pinesnake collections indicate a strong affinity for longleaf pine habitat, as most reports indicated the snakes were collected within or adjacent to longleaf pine stands (Fugler 1955, p. 24; Conant 1956, pp. 5, 19, 24; Walker 1965, p. 160; Thomas *et al* 1976, p. 253; Jennings and Fritts 1983, p. 3; Wright and Wright 1994, pp. 622, 623; Jordan 1998, p. 11). The vast majority of natural longleaf pine habitat has been lost or degraded due to conversion to extensive pine plantations and suppression of the historic fire regime. As a result, current Louisiana pinesnake habitat generally consists of sandy, well-drained soils in open canopy pine forest, which may include species such as longleaf, shortleaf, slash, or loblolly pines with a sparse midstory, and well-developed herbaceous ground cover dominated by grasses and forbs (Young and Vandeventer 1988, p. 204; Rudolph and Burgdorf 1997, p. 117).

Abundant ground-layer herbaceous vegetation is important for the Louisiana pinesnake's primary prey, the Bairds pocket gopher (*Geomys breviceps*), which constitutes 75 percent of the Louisiana pinesnake's estimated total prey biomass (Rudolph *et al* 2012, p. 243). Baird's pocket gopher depends mostly on various plant parts of a variety of herbaceous species (Pennoyer 1932, pp. 128–129; Sulentich *et al.* 1991, p. 3). Pocket gopher abundance is associated with a low density of trees, an open canopy, and a small amount of woody vegetation cover, which allow greater sunlight and more herbaceous forage for pocket gophers (Himes 1998, p. 43; Melder and Cooper 2015, p. 75).

Bairds pocket gophers also create the burrow systems in which Louisiana pinesnakes are most frequently found (Rudolph and Conner 1996, p. 2; Rudolph and Burgdorf 1997, p. 117; Himes 1998, p. 42; Rudolph *et al.* 1998, p. 146; Rudolph *et al.* 2002, p. 62; Himes *et al.* 2006, p. 107), and the snakes use these burrow systems as nocturnal refugia and hibernacula, and to escape from fire (Rudolph and Burgdorf 1997, p. 117; Rudolph *et al.* 1998, p. 147; Ealy *et al.* 2004, p. 386; Rudolph *et al.* 2007 p. 561; Pierce *et al.* 2014, p. 140). From 74 percent to greater than 80 percent of radio-tagged Louisiana pinesnake relocations have been underground in pocket gopher burrow systems (Ealy *et al.* 2004, p. 389; Himes *et al.* 2006, p. 107). In Louisiana, habitat selection by Louisiana pinesnakes seems to be determined by the abundance and distribution of pocket gophers and their burrow systems (Rudolph and Burgdorf 1997, p. 117). Active Louisiana pinesnakes occasionally use debris, logs, and low vegetation as temporary surface shelters (Rudolph and Burgdorf 1997, p. 117; Himes 1998, p. 26; Ealy *et al.* 2004, p. 386); however, most Louisiana pinesnakes disturbed on the surface retreat to nearby burrows (Rudolph and Burgdorf 1997, p. 117). Louisiana pinesnakes also minimally use decayed or burned stumps, or nine-banded armadillo (*Dasypus novemcinctus*) burrows as underground refugia (Ealy *et al.* 2004, p. 389).

Baird's pocket gophers appear to prefer well-drained, sandy soils with low clay content in the topsoil (Davis *et al.* 1938, p. 414). Whether by choice for burrowing efficiency or in pursuit of Baird's pocket gophers (or likely both), Louisiana pinesnakes also occur most often in sandy soils (Wagner *et al.* 2014, p. 152). In Wagner *et al.*'s study, modelling of Louisiana pinesnake habitat revealed that in addition to suitable forest structure and herbaceous vegetation, specific soil characteristics are an important determinant of Louisiana pinesnake inhabitance. Wagner *et al.* (2014, entire) developed a Landscape-scaled Resource Selection Functions Model of Potential Louisiana Pinesnake Habitat (LRSF-Model) using available Louisiana pinesnake location data with county and parish soil survey data as independent variables to more accurately identify the percentage of certain soil characteristics that were selected from what was available in the landscape, indicating preference. The snakes were found to prefer soils with high sand content and a low water table (Wagner *et al.* 2014, p. 152). In a separate modelling study, using essentially the same dataset but a different study method, Duran (2010, p. 11) also found that Louisiana pinesnakes prefer sandy, well-drained soils, confirming the validity of the LRSF-Model, originally proposed in 2009 (Wagner *et al.* 2009, entire).

The fire-climax park-like conditions of typical Louisiana pinesnake habitat are created and maintained by recurrent, low-intensity ground fires that occur approximately every 3 to 5 years. In the absence of recurrent fire, growth of woody midstory species is increased, and conditions supporting the Louisiana pinesnake's prey species are lost due to shading of herbaceous vegetation. Using radio-telemetry in Bienville Parish, Louisiana, Himes *et al.* (2006, p. 107) recorded wild-caught (*i.e.,* not captive-bred) Louisiana pinesnakes (nine adults and one juvenile) most frequently in pine forests (56 percent), followed by pine plantation (23 percent) and clear-cuts (9 percent). It should be noted, however, that across all sites, snakes appeared to select areas with few large trees (7 to 9 trees per plot) that were approximately 0.1 ac (0.04 ha) in size, resulting in less canopy closure and more light penetration, which supports increased understory vegetation growth and therefore more pocket gophers (Himes *et al.* 2006, pp. 108–110; 113) regardless of the type of wooded land. In a 2-year (2004–2005) trapping study of three locations (two were mixed long leaf/loblolly pine stands being managed specifically for Louisiana pinesnake habitat, and one was a loblolly pine plantation managed for fiber tree production), Reichling *et al.* (2008, p. 4) found the same number of Louisiana pinesnakes in the pine plantation (n=2) as one of the mixed pine stands managed for Louisiana pinesnake (n=2); however, of all the three trapping locations studied, the greatest number of snakes was found in the second mixed pine stand managed for Louisiana pinesnake (n=8). In addition, the snakes found in pine plantation conditions by Reichling *et al.* appeared thin or emaciated (indicating they probably had not fed recently), and were not recaptured in that habitat, which may have indicated they were moving through these sites (Reichling *et al.* 2008, pp. 9, 14). Further trapping at the same sites since the study has produced 17 and 9 more Louisiana pinesnakes for the first and second beneficially managed stands, respectively, and only 3 more for the plantation site (Pierce 2015, unpub. data).

Life History

Louisiana pinesnakes appear to be most active March through May and September through November (especially November), and least active December through February and during the summer (especially August) (Himes 1998, p. 12). During the winter, Louisiana pinesnakes use Baird's pocket gopher burrows as hibernacula (Rudolph *et al.* 2007 p. 561; Pierce *et al.* 2014, p. 140). In a study conducted by Pierce *et al.* (2014, pp. 140, 142), the species did not use burrows communally, and they did not exhibit fidelity to hibernacula sites in successive years. Louisiana pinesnakes observed in east Texas appear to be semi-fossorial and essentially diurnal, and were also relatively immobile (*i.e.,* moved less than 33 ft (10 meters (m)) on

54.5 percent of days monitored (Ealy *et al.* 2004, p. 391). In one study, they spent, on average, 59 percent of daylight hours (sunrise to sunset) below ground, and moved an average of 541 ft (163 m) per day (Ealy *et al.* 2004, p. 390). Adult males in a Louisiana study by Himes *et al.* moved an average of 495 ft (150 m) daily (longest = 3,802 ft (1,159 m)), adult females 348 ft (106 m), and juveniles 112 ft (34 m) (Himes 1998, p. 18). Himes *et al.* (2006, p. 107) documented an average home range size of 82 ac (33.2 ha) (range 16 to 267 ac (6.5 to 108 ha)) for the Louisiana pinesnake. Himes *et al.* also found that adult males had larger average home ranges (145 acres (ac) (58.7 hectares (ha))) than females (25 ac (14 ha)) and juveniles (13 ac (5.5 ha)) (Himes 1998, p. 18).

Baird's pocket gopher is the primary prey of the Louisiana pinesnake (Rudolph *et al.* 2002, p. 58), comprising an estimated 53 percent of available individual prey records (75 percent of total prey biomass) (Rudolph *et al.* 2012, p. 243). The Louisiana pinesnake exhibits specialized prey handling behavior for the burrow-dwelling pocket gopher not common among constricting snake species (Rudolph *et al.* 2002, pp. 59–61). The Louisiana pinesnake is also known to eat eastern moles (*Scalopus aquaticus*), cotton rats (*Sigmodon hispidus*), deer mice (*Peromyscus* sp.), harvest mice (*Reithrodontomys* sp.), and turtle (probably *Trachemys scripta*) eggs (Rudolph *et al.* 2002, p. 59; Rudolph *et al.* 2012, p. 244).

Louisiana pinesnake sexual maturity is attained at an approximate length of 4 ft (120 cm) and an age of approximately 3 years (Himes *et al.* 2002, p. 686). The Louisiana pinesnake is an egg-layer (oviparous), with a gestation period of about 21 days (Reichling 1988, p. 77), followed by 60 days of incubation. Having the smallest clutch size (three to five) of any North American colubrid snake, the Louisiana pinesnake exhibits a remarkably low reproductive rate (Reichling 1990, p. 221). However, the Louisiana pinesnake produces the largest eggs (generally 12 cm (5 in) long and 5 cm (2 in) wide) of any U.S. snake (Reichling 1990, p. 221). It also produces the largest hatchlings reported for any North American snake, ranging 18 to 22 in (45 to 55 cm) in length, and up to 3.77 ounces (oz) (107 grams (g)) in weight (Reichling 1990, p. 221). No Louisiana pinesnake nests have been located in the wild. Captive Louisiana pinesnakes can live over 30 years, but females have not reproduced beyond the age of 18 years (Reichling and Schad 2010, p. 5).

Historical and Current Distribution

The Louisiana pinesnake historically occurred in portions of northwest and west-central Louisiana and extreme east-central Texas (Conant 1956, p. 19). This area coincides with an isolated, and the most westerly, occurrence of the longleaf pine ecosystem and is situated west of the Mississippi River. Most of the sandy, longleaf pine-dominated savannahs historically inhabited by the Louisiana pinesnake had been lost by the mid-1930s (Bridges and Orzell 1989, p. 246; Frost 1993, p. 30). After virgin longleaf pine was cut, it rarely regenerated naturally. In some parts of the Southeast, free-ranging hogs depredated the longleaf pine seedlings, and fire suppression allowed shrubs, hardwoods, and loblolly pine to dominate (Frost 1993, pp. 34–36). The naturally maintained open structure and abundant herbaceous vegetation characteristic of the historical longleaf pine forests was diminished or lost, and, therefore, it is likely that undocumented populations of this species historically occurred but were lost before 1930.

The U.S. Forest Service (USFS), Southern Research Station (SRS), Wildlife Habitat and Silviculture Laboratory in Nacogdoches, Texas, has compiled and maintains a historical records database of all known Louisiana pinesnake locations (excluding telemetry data). According to that database, 267 occurrence records of 235 individual Louisiana pinesnakes have been verified from 1927 through December 21, 2015 (excluding reintroductions), all from Louisiana and Texas (Pierce 2015, unpub. data). By comparison, for the Florida pinesnake (*Pituophis melanoleucus mugitus*), a species with a four State range (Ernst and Ernst 2003, p. 281), there are 874 records of occurrence through 2015 in the State of Florida alone (Enge 2016, pers. comm.). Similarly, there are approximately 395 total records of black pinesnakes (*Pituophis melanoleucus lodingi*) since 1932 (Hinderliter 2016, pers.comm.).

Based on the Louisiana pinesnake database, there are records from seven parishes in Louisiana (Beauregard, Bienville, Jackson, Natchitoches, Rapides, Sabine, and Vernon) and 11 counties in Texas (Angelina, Hardin, Jasper, Nacogdoches, Newton, Polk, Sabine, San Augustine, Trinity, Tyler, and Wood) (Figure 1). Previous Louisiana pinesnake reports that are not included in this database are: single records for Calcasieu and Jefferson Davis Parishes in Louisiana (Williams and Cordes 1996, p. 35), considered suspect (Pierce 2015, unpub. data; Thomas *et al.* 1976, pp. 253–254; Walls 2008, pers. comm.); a single record from Cherokee County, Texas, which was erroneous (Pierce 2009, pers. comm.); single records from Montgomery and Walker Counties in Texas reclassified as *Pituophis catenifer* (Pierce 2008, pers. comm.); two records from Rapides Parish, Louisiana, and one from Caldwell County, Texas, from the 1960s considered not verifiable (Reichling 2012, pers. comm.; Thomas *et al.* 1976, pp. 253–254).

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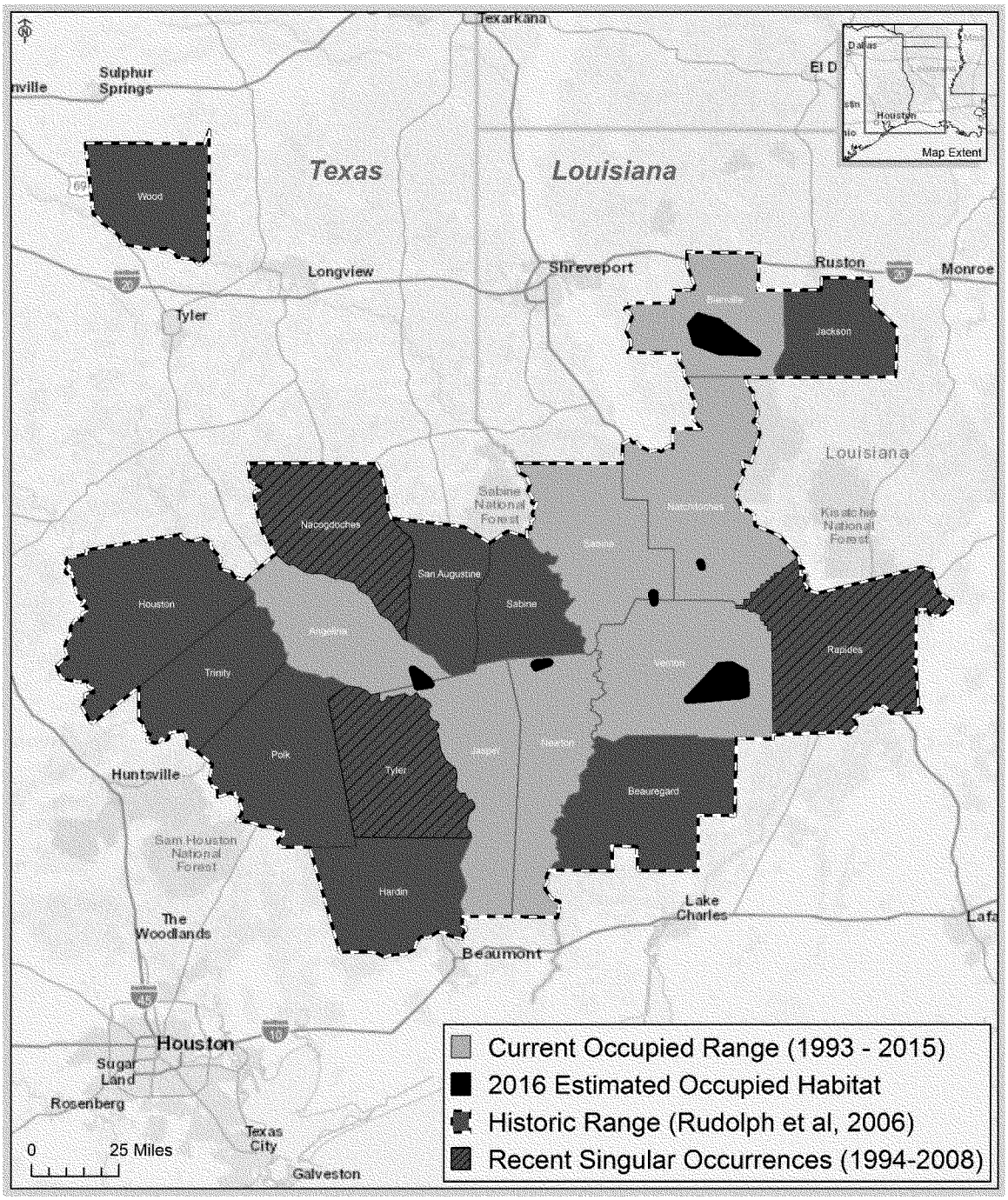
Figure 1. Current and Historic Range of Louisiana Pinesnake



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Despite being primarily diurnal, the Louisiana pinesnake's apparent rarity, secretive nature, and preference for occupying pocket gopher burrow systems has made it difficult to generate extensive natural history information (Ealy *et al.* 2004, pp. 383–384). Trapping results are functions of trap location selection, trap success, and true presence or absence; thus trapping data only approximate Louisiana pinesnake use of an area, but are the best available estimate. Currently trapping is the only standardized and most effective known method for surveying Louisiana pinesnakes. While it is the most effective, it is also expensive and labor intensive. Trapping for Louisiana pinesnakes involves the use of multiple sets of drift fences with box traps in an area either known to be inhabited by Louisiana pinesnakes or that appears to have suitable habitat. Box and funnel traps, with and without drift fences, are effective in catching snakes similar in size, and related to the Louisiana pinesnake, including the bullsnake (*Pituophis catenifer sayi*), black pinesnake, Florida pinesnake, and northern pinesnake (*Pituophis melanoleucus melanoleucus*) (Burgdorf *et al.* 2005, p. 424; Fitch 1951, p. 80; Yager *et al.* 2005, p. 24; Zappalorti 2016, p. 7; Enge 2016, pers. comm.).

Since 1993, extensive Louisiana pinesnake trapping has been conducted at first near recent recorded occurrences of the species that appeared to be in suitable habitat, and then more broadly, in other locations of varying habitat conditions within the snake's historical range (Rudolph *et al.* 2006, p. 464) by the USFS, the U.S. Army, the Memphis Zoo, and the Louisiana Department of Wildlife and Fisheries (LDWF). Trapping has been conducted to provide animals for telemetry studies, to determine the effects of vehicle-caused mortality, and for surveys to document presence of the species (Rudolph *et al.* 2015, p. 3). A variable number of traps are operated per year in 10 Texas counties and seven Louisiana parishes (Rudolph *et al.* 2015, p. 3). Through the years, there have been slight modifications to some traps, but it is not considered to have had major impacts on trap success (Rudolph *et al.* 2015, p. 3). Additionally, over time, new traps may be added to locations thought to contain Louisiana pinesnakes because of the presence of suitable conditions, such as preferred soils (Melder 2015, p. 115; Wagner *et al.* 2014, p. 152).

In total, trapping during 1993–2015 from throughout the historical range of the Louisiana pinesnake has resulted in 101 unique individual captures. Supported by rangewide trapping results and the historical records database, Rudolph *et al.* (2006, p. 467–469) concluded that the failure to document existing Louisiana pinesnake populations at known historical localities, coupled with the degradation and fragmentation of habitat in those areas, indicates that the Louisiana pinesnake had been extirpated from significant portions of its historical range. Three parishes (Beauregard, Jackson, and Rapides) in Louisiana, and seven counties (Hardin, Nacogdoches, Polk, Sabine, San Augustine, Trinity, and Wood) in Texas, are now considered unoccupied by the Louisiana pinesnake. Rudolph *et al.* (2006, pp. 467–469) determined that six occupied areas were in existence in 2006. In 2007, an area on the Kisatchie District of the Kisatchie National Forest (KNF) in Louisiana was determined to be occupied by the Louisiana pinesnake. Based on 2014 analysis (and reaffirmed by 2016 analysis) of occurrence records of counties or parishes with multiple observations since 1993, six natural, potentially extant, populations of Louisiana pinesnakes occur in four parishes (Bienville, Natchitoches, Sabine, and Vernon) in Louisiana, and three counties (Angelina, Jasper, and Newton) in Texas. Louisiana pinesnake habitat currently considered occupied (based upon 1993–2015 occurrence data) is primarily concentrated on public lands controlled by the Department of Defense (DOD) (Joint Readiness Training Center and Fort Polk [Fort Polk] and Peason Ridge), the USFS (KNF and Angelina National Forest [ANF]), and privately owned industrial timberlands in Louisiana and Texas. There is also a reintroduction feasibility-study population of Louisiana pinesnakes that has been established from captive-bred snakes in Grant Parish, Louisiana, on KNF lands.

Although single observations were not used to establish known occupied areas, single individuals have been documented in one Louisiana parish and two Texas counties (see Figure 1, above). A single Louisiana pinesnake was observed crossing a road in 1994 in Tyler County, but no others have been recorded in that county in the 22 years since that observation. A single observation of a Louisiana pinesnake found dead along a road in 2001 indicates that the current population in Natchitoches Parish may have extended into extreme northwestern Rapides Parish, Louisiana; however, no more have been sighted in Rapides Parish since 2001. A juvenile Louisiana pinesnake was captured in 2008, in Nacogdoches County near Garrison, Texas (Pierce 2015, unpub. data), suggesting that at least some individuals existed near that site as recently as 8 years ago.

To estimate the size of occupied habitat areas, all Louisiana pinesnake records from 1993 to 2015 (Pierce 2015, unpub. data) containing location data and meeting the criteria established below (157 records), were plotted in a Geographic Information System (GIS). Using ArcMap (Version 10.2.1), a minimum convex polygon (MCP) was drawn around clusters of records, and a 0.6-mile (mi) (1.0-kilometer (km)) buffer was drawn around each MCP, resulting in the estimated occupied habitat area (EOHA) for Louisiana pinesnakes represented by that group of records. The MCP was buffered to accommodate the fact that trap locations were not placed on the landscape with the intent of delineating population boundaries. A 0.6-mi (1.0-km) buffer was used because telemetry data indicate this is a reasonable approximation of the area that a Louisiana pinesnake uses during 1 or more years (Rudolph 2008a, pers. comm.). After discussions with experts, including Dr. Craig Rudolph and members of the Association of Zoos and Aquariums (AZA), the Service developed criteria to determine the data and methodology to be used for estimating the boundaries of the EOHAs.

All Louisiana pinesnake verified occurrence records were used for EOHA analysis except for: Those obtained prior to 1993 (before extensive trapping began); and records older than 11 years (from the time of analysis; which is the estimated Louisiana pinesnake generational turnover period (Marti 2014, pers. comm.)), when traps within 0.6 mi (1 km) of those records had been unproductive for 5 years of trap effort following the date of the records.

That methodology uses records (including non-trap occurrence) obtained over a period of intense surveys during the estimated generational time of Louisiana pinesnakes in captivity. However, some records that are located in areas potentially still occupied by the species, where habitat attributes have remained similar or improved since observed occurrence, are not used for this estimation of occupied range because significant trapping efforts have not produced any additional records in that area.

The original purpose of the EOHAs designation was to match proactive habitat management activities to areas most likely to be currently occupied by the Louisiana pinesnake (U.S. Fish and Wildlife Service 2014, p. 8). Based on the previously described methodology, the following EOHAs have been delineated (Figure 2): (1) The Bienville EOHA located on privately owned industrial timberlands in Bienville Parish, Louisiana; (2) the Kisatchie EOHA located on USFS lands (the Kisatchie Ranger District of the KNF in Natchitoches Parish, Louisiana); (3) the Peason Ridge EOHA located on DOD lands (Vernon and Sabine Parishes) and a small amount of private lands (inholdings) in Louisiana; (4) the Fort Polk/Vernon EOHA located on DOD lands (Fort Polk), USFS lands (the Vernon Unit/Calcasieu District of the KNF), and a small amount of private lands (inholdings) in Vernon Parish, Louisiana; (5) the Scrappin' Valley EOHA located primarily on privately owned timberlands in Newton County, Texas; (6) the Angelina EOHA located on USFS lands (the southern section of ANF in Angelina and Jasper Counties) and private lands in Texas; and (7) the Catahoula Reintroduction Feasibility EOHA located on USFS lands (the Catahoula Ranger District of the KNF in Grant Parish, Louisiana). Utilizing the methods described above, the Winn Ranger District of the KNF in Natchitoches Parish, Louisiana, and the Sabine National Forest in Sabine

County, Texas, identified in 2008, are no longer considered occupied.

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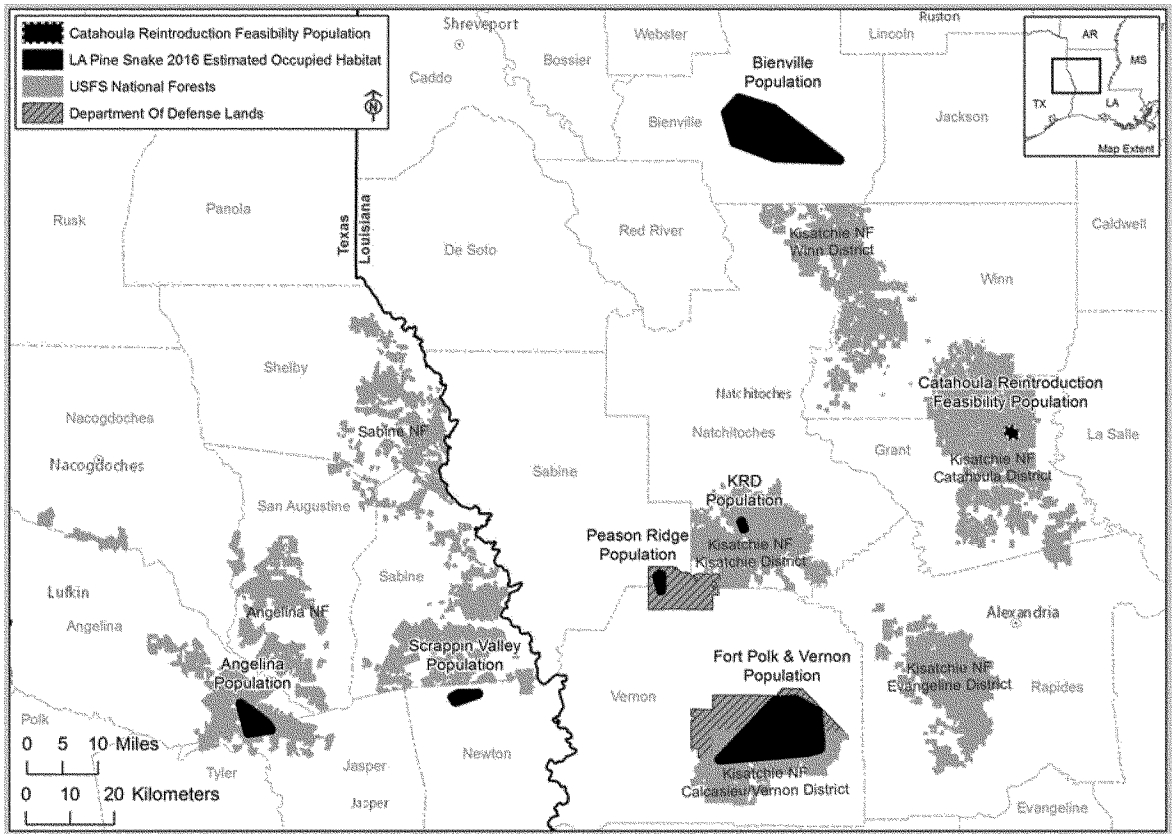
Figure 2: Estimated Occupied Habitat Areas 2016



BILLING CODE 4333–15–C

Those EOHAs occur on 30,751.9 ac (12,444.8 ha) of DOD lands, 47,101.3 ac (19,061.2 ha) of USFS lands, 499.7 ac (202.2 ha) of State and municipal lands, and 67,324.9 ac (27,245.4 ha) of private lands (Table 1).

TABLE 1—LAND OWNERSHIP IN ACRES (HECTARES) OF ESTIMATED LOUISIANA PINESNAKE OCCUPIED HABITAT AREAS AS DETERMINED FOR 2016 ACCORDING TO LOCATION RECORDS THROUGH 2015

[Totals may not sum to rounding]

State	Estimated occupied habitat area	U.S. Forest Service	Department of Defense	State and municipal	Private	Total for estimated occupied habitat area
Louisiana	Bienville	0 (0)	0 (0)	363.7 (147.2)	60,727.2 (24,575.5)	61,090.9 (24,722.6)
	Kisatchie	1,598.8 (647.0)	0 (0)	0 (0)	0 (0)	1,598.8 (647.0)
	Peason Ridge	0 (0)	3,147.3 (1,273.7)	0 (0)	0 (0)	3,147.3 (1,273.7)
	Fort Polk/Vernon	34,164.7 (13,826.0)	27,601.3 (11,169.8)	0 (0)	222.6 (90.1)	61,988.7 (25,085.9)
	Catahoula Reintroduction	1,828.5 (739.9)	0 (0)	0 (0)	0 (0)	1,828.5 (739.9)
Louisiana Total		37,592.0 (15,213.0)	30,748.5 (12,443.5)	363.7 (147.2)	60,949.9 (24,665.6)	129,654.1 (52,469.2)
Texas	Scrappin' Valley	0 (0)	0 (0)	21.3 (8.6)	5,036.5 (2,038.2)	5,057.8 (2,046.8)

TABLE 1—LAND OWNERSHIP IN ACRES (HECTARES) OF ESTIMATED LOUISIANA PINESNAKE OCCUPIED HABITAT AREAS AS DETERMINED FOR 2016 ACCORDING TO LOCATION RECORDS THROUGH 2015—Continued

[Totals may not sum to rounding]

State	Estimated occupied habitat area	U.S. Forest Service	Department of Defense	State and municipal	Private	Total for estimated occupied habitat area
	Angelina	9,509.3 (3,848.3)	3.3 (1.4)	114.7 (46.4)	1,338.6 (541.7)	10,965.8 (4,437.7)
Texas Total		9,509.3 (3,848.3)	3.3 (1.4)	136.0 (55.1)	6,375.0 (2,579.9)	16,023.6 (6,484.5)
Total Ownership		47,101.3 (19,061.3)	30,751.9 (12,444.8)	499.7 (202.2)	67,324.9 (27,245.4)	145,677.7 (58,953.7)

Population Estimates and Status

The Louisiana pinesnake is recognized as one of the rarest snakes in North America (Young and Vandeventer 1988, p. 203; Himes *et al.* 2006, p. 114). It was classified in 2007 as endangered on the International Union for Conservation of Nature's (IUCN's) Red List of Threatened Species (version 3.1; *http://www.iucnredlist.org/*).

Most Louisiana pinesnake records that were used to approximately delineate occupied habitat for 2016 were acquired by trapping. We considered each day that a trap was open a ''trap day.'' Thus, for an area being surveyed, all traps in that area that were open contribute to the number of trap days (*i.e.,* four traps that are open for 3 days each equals 12 trap days). The ratio of trap days and number of unique snakes captured is called ''trap success'' (*i.e.,* two unique snakes captured during 2,000 trap days = 1 capture per 1,000 trap days or a 1:1,000 trap success) and was determined for each population. Louisiana pinesnake trapping across the species' entire range (including areas outside of EOHAs in Louisiana and Texas) during 1993 through 2015 has resulted in 101 unique individual captures during 448,892 trap days (1:4,444 trap success) (Pierce 2016a, pers. comm.). Trapping information can be compared to similar species to get a sense of the relative rarity of this species when compared to a similar species trapped in a comparable way. For instance, a Florida pinesnake trapping effort using similar drift fence trapping methods in one 30,000-ac (12,141-ha) section of the species' range captured 87 unique individuals during 50,960 trap days (1:585.7 trap success) over a 13-year period from 2003 to 2015 (Smith 2016b, pers. comm.). The Louisiana pinesnake site with the greatest long-term trap success by far, the Bienville EOHA, which is 61,090.9 ac (24,722.6 ha), has a trap success rate of 1:854.0 between 1993 and 2015 (Pierce 2016a, pers. comm.), which is substantially lower than those found in Smith's study of Florida pinesnake. Actual population densities cannot be reliably estimated from trapping data because mark-recapture analyses cannot be conducted without sufficient numbers of Louisiana pinesnake recaptures, but similar trapping methods have been used by others to estimate snake abundance.

All Louisiana pinesnake EOHAs contain at least some suitable habitat, and experience varying amounts of beneficial forest management. However, most populations appear to show either a decline or no conclusive change in trap success through time, indicating that numbers of individuals in most populations are likely decreasing (Rudolph *et al.* 2015, p. 8). Despite continued effort, some populations have not experienced trap success or other occurrence records for many years. For this reason, as discussed earlier, the Winn Ranger District of the KNF portion of the Bienville EOHA and the Sabine EOHA are no longer considered occupied. Trapping efforts (all provided by Pierce (2015, unpub. data)) and habitat management actions are presented below for each EOHA.

Bienville EOHA

Based on trap and other occurrence records (84 occurrences (including trap recaptures) from 1988 through 2015) (Pierce 2015, unpub. data), the Bienville population is widely believed to be the largest extant Louisiana pinesnake population (Rudolph *et al.* 2006, p. 465; Reichling *et al.* 2008, p. 10). For all trapping efforts so far (1995 through 2015, not continuous), trap success for this population was 1:854. While trap success varies annually, the trap success in this area has been consistently greater than for any other population overall. Trapping on that private timberland has only recently resumed in 2012, after cessation in 2009. The Kepler Lake area of the Bienville EOHA has produced the best trap success of any trapping area in areas currently known to be inhabited by the species. Consequently, Reichling *et al.* (2008, p. 10) believed this site was critical for the preservation of this species. Trapping from a previous effort on the Winn District portion of this population between 2000 and 2001 provided two captures (in addition to one recapture). Trap efforts in the same area from 2004 to 2013 have produced zero captures in 7,525 trap days, and the area is now regarded as unoccupied.

Within the privately owned timberland described above, two disjunct areas are managed for the Louisiana pinesnake with thinning, longleaf pine restoration, targeted herbicide use, and prescribed burning (see ''Conservation Efforts to Reduce Habitat Destruction, Modification, or Curtailment of Its Range,'' below).

Kisatchie EOHA

Two relatively recent Louisiana pinesnake occurrence records (one non-capture sighting (2003) and one hand-capture (2007)) exist for this population. No Louisiana pinesnakes were captured during 12,011 trap days (1997 to 2003) on the Kisatchie District of the KNF. However, past trapping did not occur in the locations of the records mentioned above. Furthermore, despite the presence of substantial amounts of suitable habitat on the Kisatchie District, past trapping did not sample the best habitat (Rudolph *et al.* 2006, p. 469). Trapping resumed within this population in 2012, in the best habitat, and has continued through 2015, but no captures (by hand or trap) have occurred since the 2007 capture (Pierce 2015, unpub. data).

Active habitat management for the endangered red-cockaded woodpecker (*Picoides borealis*) and the Louisiana pinesnake occur within and surrounding the EOHA of this population (see ''Conservation Efforts to

Reduce Habitat Destruction, Modification, or Curtailment of Its Range,'' below).

Peason Ridge EOHA

Six occurrence records (from 2003 to 2013, all observed after 2005) exist for this population; one of which was a non-trap sighting. The trapping effort for the last 5 years (2009 to 2013 (8,446 trap days)) produced four captures, one in 2010, two in 2012, and one in 2013, with a success rate of 1:2,112 (Pierce 2015, unpub. data).

Active habitat management for the red-cockaded woodpecker and the Louisiana pinesnake occurring at this site has stabilized or increased the amount of preferable habitat that exhibits suitable vegetative characteristics (see ''Conservation Efforts to Reduce Habitat Destruction, Modification, or Curtailment of Its Range,'' below).

Fort Polk/Vernon EOHA

Twenty-two occurrence records from 2003 to 2013, including four non-trap sightings and four trap-recaptures, exist for this population. Trap success for this population over 5 years (2009 to 2013) is estimated to be 1:2,625 (eight unique individual captures out of 21,003 trap days), which includes all recent unsuccessful surveying on the Vernon Unit of the KNF. Since 2003, no captures have occurred on the Vernon Unit. Excluding trapping on the Vernon Unit, DOD observed a trap success rate over 5 years (2009 to 2013) of 1:1,959 (eight unique individual captures during 15,672 trap days) on DOD property (Pierce 2015, unpub. data). Two snakes were trapped in 2014, and there were three records of occurrence in 2015 (one hand-captured and two dead on roads).

Active habitat management for the red-cockaded woodpecker and the Louisiana pinesnake has stabilized or increased the amount of habitat that has suitable vegetative characteristics (see ''Conservation Efforts to Reduce Habitat Destruction, Modification, or Curtailment of Its Range,'' below).

Scrappin' Valley EOHA

On this primarily private land, five occurrence records during 2005 to 2015 exist for this population; however, two of those were road mortalities, two were removed from the wild for captive breeding, and one was sighted but not captured. There have been no trap captures since 2009 during 15,628 trap days within this population and no other occurrences. During trapping efforts on this land from 1995 to 1997, five captures occurred during 2,128 trap days (a success rate of 1:426), demonstrating a reduction of trap success at this site (Pierce 2015, unpub. data).

Active habitat management for the red-cockaded woodpecker and the Louisiana pinesnake occurs at this site (see ''Conservation Efforts to Reduce Habitat Destruction, Modification, or Curtailment of Its Range,'' below).

Despite Louisiana pinesnake occurrences as recent as 2008, and proactive habitat management by the former and current private landowners, the lack of recent trap success when compared to trap success in the 1990s suggests that this population has declined due to prolonged minimal suitable habitat availability.

Angelina EOHA

Seven occurrence records during 2003 to 2013 exist for this population. Four were unique trap captures, one was a trap recapture, one was hand-caught alive on a road, and one previously captured and pit-tagged individual was found dead on a road in 2009. Both the trap recapture and hand-caught individual were removed from the wild for captive breeding. From 2009 to 2013, no unique trap captures have occurred within this population during 16,277 trap days. The most recent unique individual trap capture at this site was in 2007. However, a recapture did occur within this population as recently as 2012, and that individual was removed from the wild for captive breeding. Trap success rates have shown a steady decline throughout the effort period: From 1992 to 1997, success rate was 1:652 (2 captures during 1,303 trap days); during 1998 to 2005, success rate was 1:3,420 (2 captures during 6,840 trap days); and during 2007 to 2012, success rate was 1:5,305 (3 captures during 15,916 trap days). However, all trap effort within this population produced only a total of seven unique individual Louisiana pinesnakes since the 1990s (27,656 trap days) (Pierce 2015, unpub. data).

Active habitat management for the red-cockaded woodpecker and the Louisiana pinesnake occurs at this site (see ''Conservation Efforts to Reduce Habitat Destruction, Modification, or Curtailment of Its Range,'' below).

Catahoula Reintroduction Feasibility EOHA

An informal committee was established to oversee and conduct an experimental reintroduction of the Louisiana pinesnake in an attempt to demonstrate the feasibility of reintroducing a population using individuals from a captive population, and establishment of a viable population in restored habitat. In total, 77 captive-bred Louisiana pinesnakes (11 in 2010, 15 in 2011, 3 in 2012, 15 in 2013, 1 in 2014, 15 in 2015, and 17 in 2016) have been released into the wild at the Catahoula Ranger District of the KNF (Pierce 2016, unpub. data; Pierce 2016b, pers. comm.; Smith 2016a, pers. comm.). This area is not near any known Louisiana pinesnake populations and not within the known historical range of the species. Detection of released snakes is occurring within this EOHA through monitoring of deployed Automated PIT Tag Recorders (APTRs) and trapping. Prior to March 22, 2016, 60 snakes have been released, and as of that date a total of 26 individual snakes have been detected at least once after release (detections beginning 1 day after release): of those, 14 snakes have been detected alive more than 60 days after release, of those, 10 have been detected alive in the year following the winter after release, of those, 7 have been detected 2 years (winters) after release, of those, 3 have been detected 3 years (winters) after release, and of those, 1 snake has been detected 4 years (winters) after release (Pierce 2016b, pers. comm.; Pierce 2016c, pers. comm.).

Active habitat management for the red-cockaded woodpecker and the Louisiana pinesnake occurs at the Catahoula Ranger District site (see ''Conservation Efforts to Reduce Habitat Destruction, Modification, or Curtailment of Its Range,'' below).

Captive-Breeding Population

The captive Louisiana pinesnake zoo population established in 1984 was initially maintained through wild collection. The AZA Species Survival Plan (SSP) for the Louisiana pinesnake was implemented in 2000, to manage the zoo population (Reichling *et al., in litt.* 2015, p. 1). The goals of the SSP are to: Maintain an assurance colony for wild Louisiana pinesnake populations, preserve or increase genetic heterozygosity into the future, preserve representative genetic integrity of wild populations, and provide individuals as needed for research and repopulation for the conservation of wild populations (U.S. Fish and Wildlife Service 2013, pp. 32–33). As of March 2016, the captive-breeding Louisiana pinesnake population consists of 111 individuals (51 males, 53 females, and 7 unsexed individuals) in 18 AZA accredited institutions and 2 non-AZA partner institutions (Reichling 2016, pers. comm.). Initially, three populations were managed based on their different geographic origins, which are separated

by rivers (one from Texas, separated from Louisiana by the Sabine River, and two from Louisiana, which are separated by the Red River) (Reichling and Schad 2010, p. 1). Recent genetic analyses showed that all populations were similar in population structure and the Texas and southern Louisiana populations were difficult to separate genetically (Kwiatkowski *et al.* 2014, p. 12). Therefore, currently one group is derived from Bienville Parish, Louisiana, founders and the other group is a combination of Vernon Parish, Louisiana, and eastern Texas snakes (Reichling 2016, pers. comm.).

Summary of Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination. In this section, we summarize the biological condition of the species and its resources, and the influences of the listing factors on them, to assess the species' overall viability and the risks to that viability.

Factor A: The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Both the quantity and quality of the natural longleaf pine ecosystem, the primary historical habitat of the Louisiana pinesnake, have declined sharply in Louisiana and Texas since European settlement. The loss, degradation, and fragmentation of the longleaf pine dominant ecosystem was historically caused by logging, turpentining, fire suppression, alteration of fire seasonality and periodicity, conversion to generally off-site pine species plantations, agriculture, and free-range hogs (Frost 1993, pp. 24–30, 31, 35). Virtually all virgin timber in the southern United States was cut during intensive logging from 1870 to 1920 (Frost 1993, p. 30). Only about 2.9 percent of longleaf pine forests in Louisiana and Texas were uncut old-growth stands in 1935 (Bridges and Orzell 1989, p. 246). During the latter half of the 20th century, Louisiana, Alabama, and Mississippi lost between 60 and 90 percent of their already reduced longleaf acreage (Outcalt and Sheffield 1996, pp. 1–10). By the late 1980s, the natural longleaf pine acreage in Louisiana and Texas was only about 15 and 8 percent, respectively, of what had existed in 1935 (Bridges and Orzell 1989, p. 246). Those longleaf pine forests were primarily converted to extensive monoculture pine plantations (Bridges and Orzell 1989, p. 246), which presumably were not primarily managed for enhancement of herbaceous vegetation.

In short, the longleaf dominant pine forest (longleaf pine forest type plus longleaf pine in mixed species stands) in the southeastern United States declined approximately 96 percent from the historical estimate of 92 million ac (37 million ha) (Frost 1993, p. 20) to approximately 3.75 million ac (1.52 million ha) in 1990 (Guldin *et al.* 2016, p. 324). Since the 1990s, longleaf pine dominant forest acreage has been trending upward in parts of the Southeast through restoration efforts (Guldin *et al.* 2016, pp. 323–324). By 2010, the longleaf dominant pine forest stands had increased to approximately 4.3 million ac (1.7 million ha) (Oswalt *et al.* 2012, p. 10; Guldin *et al.* 2016, pp. 323–324). A recent estimate for the extent of longleaf dominant pine forest in 2015 was 4.7 million ac (2.8 million ha) (America's Longleaf Restoration Initiative 2016, p. 12).

In general, southern forest futures models predict declines of overall forest land area in the southeastern United States between 2 and 10 percent in the next 50 years (Wear and Greis 2013, p. 78). The model-projected losses of natural pine forest in the Southeast would be mostly the result of conversion to planted pine forests (Wear and Greis 2013, p. 79). For the southern Gulf region, model runs assuming high levels of urbanization and high timber prices predict large percentage losses in longleaf pine in some parishes and counties of Louisiana and Texas that were historically and that are currently occupied by the Louisiana pinesnake, while two Louisiana parishes in the current occupied range are expected to gain (less than the percent decline predicted in the other parishes and counties) in longleaf pine acreage (Klepzig *et al.* 2014, p. 53). The outer boundary or ''footprint'' of the longleaf pine ecosystem across its historical range has contracted as recently as the period of 1990 to 2010, with losses (primarily due to conversion to loblolly pine) in western Louisiana and eastern Texas (Oswalt *et al.* 2012, pp. 10–14).

Impacts from urbanization are not consistent throughout the Southeast, and most population growth is predicted to occur near major cities (Wear and Greis 2013, p. 21), which are generally not near known Louisiana pinesnake occurrences; however, the most recent assessment still predicts decreased use of land for forests (mainly due to urbanization) in the next 45 years in all of the parishes (Louisiana) and counties (Texas) historically and currently occupied by the species (Klepzig *et al.* 2014, pp. 21–23).

High-quality longleaf pine forest habitat, which is generally characterized by a high, open canopy and shallow litter and duff layers, is maintained by frequent, low-intensity fires, which in turn restrict a woody midstory and promote the flowering and seed production of fire-stimulated groundcover plants (Oswalt *et al.* 2012, pp. 2–3). The Louisiana pinesnake was historically associated with natural longleaf pine forests, which were maintained in good condition by natural processes and have the abundant herbaceous vegetation necessary to support the Louisiana pinesnake's primary prey, the Baird's pocket gopher (Himes 1998, p. 43; Sulentich *et al.* 1991, p. 3; Rudolph and Burgdorf 1997, p. 17). Based on trapping surveys and location records, it appears that areas managed with silvicultural practices for fiber production that do not allow sufficient herbaceous vegetation growth do not support viable Louisiana pinesnake populations (Rudolph *et al.* 2006, p. 470) because the snake's pocket gopher prey requires herbaceous vegetation for forage.

Rudolph *et al.* (2006, p. 467) assessed habitat conditions during 1999 and 2000, at the locations of all historical Louisiana pinesnake records (n = 118 localities) known at that time. They found that 70 percent (26 of 37) of the localities on public lands met their criteria as excellent or good condition, whereas only 33 percent (27 of 81) of the localities on private lands met their criteria as excellent or good condition. Due to habitat fragmentation, most sites with excellent or good habitat were isolated and small (typically a few hundred hectares, or less (Rudolph *et al.* 2006, p. 466)). The distribution of Louisiana pinesnakes within the current range was further restricted because intensive land use activities and the disruption of natural fire regimes had decreased the quantity and quality of the intervening areas as habitat for this species (Rudolph *et al.* 2006, p. 470). Based on the low capture rates reported during trapping from 1993 to 2001, and the limited habitat availability, Rudolph

et al. (2006, p. 468) concluded that remnant Louisiana pinesnake populations are not large. In fact, during this 9-year trapping period, only 24 unique captures of Louisiana pinesnakes occurred out of 2,372 total unique snake captures in 101,828 trap days (a trap success of 1:3,775 for Louisiana pinesnake). At many sites, no pinesnakes were captured, but even at sites where they were captured, the average trap success was only 1:733 (Rudolph *et al.* 2006, p. 465).

The disruption of natural fire regimes, due to fire suppression and inadequate, infrequent prescribed burning, is the leading factor responsible for the degradation of the small amount of remaining suitable longleaf pine forest habitat (Rudolph and Burgdorf 1997, p. 118; Rudolph 2000, p. 7). In the absence of frequent and effective fires, upland pine savannah ecosystems rapidly develop a midstory of hardwoods and other overstory species that suppress or eliminate any herbaceous understory. As the presence of pocket gophers is directly related to the extent of herbaceous vegetation available to them, their population numbers and distribution decline as such vegetation declines, which in turn directly impacts the number and distribution of Louisiana pinesnakes. The use of prescribed burning has decreased on private timberlands because of legal liability and the expense of liability insurance, the planting of pine species which have a reduced tolerance to fire, limited funds and personnel, and smoke management issues. According to Wear and Greis (2013, p. 509), southern forests are likely to see increasing challenges to prescribed burning in the future as land-use changes involving fuels management, increased urban interface, and revised safety and health regulations will continue to constrain prescribed fire efforts. Some of these constraints could be in the form of reduced fire intervals or reductions in average area burned per fire event (strategies often used in management of pine plantations), which may not provide adequate fire intensity or frequency to suppress the overgrown understory and midstory conditions that limit herbaceous vegetation growth.

Overstory species other than longleaf pine can be managed to provide suitable understory for pocket gophers, but this is generally more difficult, as these species lack the physical characteristics and ecological adaptations to sustain desired understory conditions during all life stages, especially when managed with prescribed fire. Specifically, longleaf pine is adapted to thrive with frequent fire during all life stages, which allows continual maintenance of herbaceous communities. Other pine species lack these adaptations to fire that allow for frequent fire during all life stages (especially very young trees). Non-longleaf pine communities can be managed to provide suitable habitat within a stand when burning is not recommended (*e.g.,* very young trees) by using herbicides and other techniques. However, if those techniques alter the composition or density of the groundcover vegetation and pocket gophers decline in response, it is likely that Louisiana pinesnakes will decline in response as well (USFWS 2001). In addition, longleaf pine structure (*e.g.,* branch and needle structure) naturally allows more sunlight penetration at similar stem densities than other pine species.

Regardless of the methods used to promote herbaceous vegetation in the understory, the amount and types of herbaceous vegetation are limited by the amount of sunlight able to reach the forest floor and, for some species, by the presence of fire (*i.e.,* to scarify seeds, promote seed production, and consume leaf litter). Therefore, conversion and management of overstory vegetation that does not provide for continued maintenance of herbaceous vegetation in otherwise suitable habitat will further limit habitat available to the Louisiana pinesnake.

Habitat fragmentation threatens the continued existence of all Louisiana pinesnake populations, particularly those on private lands. This is frequently the result of urban development, conversion of longleaf pine sites to intensively managed pine plantations, and an increase in the number of roads. When patches of available habitat become separated beyond the dispersal range of a species, small populations may become less resilient because additions of individuals to the population may decline along with their potential genetic diversity contributions, thus increasing the risk of extirpation (see discussion under *Factor E: Other Natural or Manmade Factors Affecting Its Continued Existence*).

In summary, habitat loss and continuing degradation of the Louisiana pinesnake's habitat remain a significant threat to this species' continued existence.

Conservation Efforts To Reduce Habitat Destruction, Modification, or Curtailment of Its Range

When considering whether or not to list a species under the Act, we must identify existing conservation efforts and their effect on the species. In this section, we describe the extensive habitat restoration efforts that have occurred on Federal lands throughout the range (to a lesser extent on private lands) that have reduced the threat of habitat loss for some populations. We also discuss the lack of a definitive positive response of the Louisiana pinesnake to these efforts, at present.

Existing and Planned Conservation Efforts: As early as the 1980s, forest restoration and management had been implemented on Fort Polk, Peason Ridge, and adjacent USFS lands to restore and maintain conditions of widely spaced trees, clear of dense midstory growth (U.S. Department of the Army 2014, p. 21). Management occurred for training suitability and red-cockaded woodpecker habitat, and most recently for Louisiana pinesnake habitat. The requirements for those three objectives happen to have significant overlap, especially the maintenance of open canopy pine forest.

USFS has also implemented habitat restoration and management for many years on Sabine National Forest (SNF), ANF, and KNF to benefit the red-cockaded woodpecker, as provided for in its land and resource management plans (USFS 1996, pp. 107–134; USFS 1999, pp. 2–61 to 2–73). In 2003, a candidate conservation agreement (CCA) for the Louisiana pinesnake, which includes the Service, USFS, DOD, Texas Parks and Wildlife Department (TPWD), and LDWF, was completed. Targeted conservation actions are currently being implemented as part of that agreement. The CCA is designed to identify and establish beneficial habitat management actions for the Louisiana pinesnake on Federal lands in Louisiana and Texas, and provides a means for the partnering agencies to work cooperatively on projects that avoid and minimize impacts to the species. The CCA also set up mechanisms to exchange information on successful management practices and coordinate research efforts. SNF [Sabine Louisiana pinesnake population considered extirpated since 2014] and ANF in Texas, and KNF and Fort Polk in Louisiana, agreed in the CCA to continue or start new stem thinning and prescribed burning operations in sections of upland pine forests and, where possible, to convert forests to longleaf pine (CCA 2003, p. 12–16).

Since completion of the CCA, beneficial forest management activities conducted by USFS and Fort Polk have been formally dedicated to conservation of the Louisiana pinesnake. Removing some trees from a dense stand with heavy canopy cover allows more light to reach the ground, which can promote

the growth of herbaceous vegetation, an important food source for the primary prey of the Louisiana pinesnake. Prescribed burning helps to control midstory cover, particularly hardwood species that compete with pine seedlings and reduce light penetration. Converting forests to longleaf pine is helpful because longleaf pine is better adapted to fire (and tolerates it at an earlier age) than other pine species, and therefore is generally easier to manage with prescribed fire over multiple rotations. Historically, Louisiana pinesnakes were predominantly found in longleaf pine forests, and that forest type was historically the dominant type in the areas that now make up the KNF, ANF, and Fort Polk.

The CCA was revised in 2013, and now also includes the U.S. Department of Agriculture's (USDA) Natural Resources Conservation Service (NRCS) and the AZA as cooperators (U.S. Fish and Wildlife Service 2013, pp. 7–8). That agreement updates, supersedes, and improves upon the 2003 CCA, and uses significant new information derived from research, threats assessments, and habitat modeling that was not available in 2003 to focus conservation actions, including beneficial forest management, in areas with the best potential to become suitable habitat for the Louisiana pinesnake. Those areas are called habitat management units (HMUs), and they were delineated based on existing red-cockaded woodpecker habitat management areas (HMAs) in upland pine forests. Those areas were further defined by the location of preferable and suitable soils (LRSF-Model) for the Louisiana pinesnake in order to dedicate resources to areas the species is most likely to inhabit. However, the updated CCA addresses threats from habitat loss only on Federal lands, and for the activities performed by NRCS on private land. The CCA also includes guidance on practices to reduce impacts to Louisiana pinesnakes from vehicles on improved roads and off-road all-terrain vehicle (ATV) trails (see ''Conservation Efforts To Reduce Threats Under Factor E,'' below).

Thousands of acres of forests on Federal lands have been treated over many years with prescribed burning, and that treatment along with tree thinning continues to the present. The following tables summarize recent forest management activities on Federal lands where Louisiana pinesnake populations occur. Values have been rounded to the nearest acre.

TABLE 2—ACRES (HECTARES) OF PRESCRIBED BURNING AND THINNING CONDUCTED IN THE KISATCHIE RANGER DISTRICT OF THE KNF (KISATCHIE POPULATION) WITHIN THE 2014 DELINEATED EOHA (1,599 TOTAL AC [647 HA]) AND THE LARGER SURROUNDING HMU (36,114 TOTAL AC [14,615 HA])

Area	Prescribed burning 2015	Prescribed burning 2013–2015	Stocking reduction (thinning) 2015
EOHA	963 (390)	1,980 (801)	0 (0)
HMU	4,285 (1,734)	24,893 (10,074)	193 (78)

TABLE 3—ACRES (HA) OF PRESCRIBED BURNING AND THINNING CONDUCTED IN THE VERNON UNIT OF THE KNF (FORT POLK/VERNON POPULATION) WITHIN THE 2014 DELINEATED EOHA (34,487 TOTAL ACRES [13,956 HA]) AND THE LARGER SURROUNDING HMU (61,387 TOTAL ACRES [24,842 HA])

Area	Prescribed burning 2015	Prescribed burning 2013–2015	Stocking reduction (thinning) 2015
EOHA	12,670 (5,127)	43,281 (17,515)	1,541 (624)
HMU	20,734 (8,391)	74,927 (30,322)	1,670 (676)

TABLE 4—ACRES (HA) OF PRESCRIBED BURNING AND THINNING CONDUCTED AT FORT POLK (FORT POLK/VERNON POPULATION) WITHIN THE 2014 DELINEATED EOHA (27,502 TOTAL ACRES [11,130 HA]) AND THE LARGER SURROUNDING HMU (29,037 TOTAL ACRES [11,751 HA])

Area	Prescribed burning 2015	Prescribed burning 2013–2015	Stocking reduction (thinning) 2015
EOHA	7,675 (3,106)	22,628 (9,157)	430 (174)
HMU	9,159 (3,707)	24,241 (9,810)	586 (237)

TABLE 5—ACRES (HECTARES) OF PRESCRIBED BURNING AND THINNING CONDUCTED AT PEASON RIDGE (PEASON RIDGE POPULATION) WITHIN THE 2014 DELINEATED EOHA (4,886 TOTAL AC [1,977 HA]) AND THE LARGER SURROUNDING HMU (11,265 TOTAL AC [4,559 HA])

Area	Prescribed burning 2015	Prescribed burning 2013–2015	Stocking reduction (thinning) 2015
EOHA	489 (198)	2,597 (1,051)	0 (0)
HMU	2,651 (1,073)	7,440 (3,011)	100 (40)

TABLE 6—ACRES (HA) OF PRESCRIBED BURNING AND THINNING CONDUCTED IN ANF (ANF POPULATION) WITHIN THE 2014 DELINEATED EOHA (10,966 TOTAL AC [4,438 HA]) AND THE LARGER SURROUNDING HMU (24,200 TOTAL AC [9,793 HA])

Area	Prescribed burning 2015	Prescribed burning 2013–2015	Stocking reduction (thinning) 2015
EOHA	2,735 (1,107)	10,179 (4,119)	0 (0)
HMU	6,702 (2,712)	18,940 (7,665)	0 (0)

TABLE 7—ACRES (HECTARES) OF PRESCRIBED BURNING AND THINNING CONDUCTED IN THE CATAHOULA RANGER DISTRICT KNF (CATAHOULA REINTRODUCTION FEASIBILITY POPULATION) WITHIN THE 2014 DELINEATED EOHA (1,828 TOTAL AC [740 HA]) AND THE LARGER SURROUNDING HMU (57,394 TOTAL AC [HA])

Area	Prescribed burning 2015	Prescribed burning 2011–2015	Stocking reduction (thinning) 2015
EOHA	784 (317)	784 (317)	0 (0)
HMU	8,279 (3,350)	40,419 (16,357)	231 (93)

Within the Bienville EOHA, the 851-ac (344-ha) Kepler Lake and 859-ac (348-ha) Sandylands Core Management Areas (CMAs) (approximately 2.8 percent of the EOHA) were voluntarily established by the landowners at the time to be managed for Louisiana pinesnake habitat. According to the current landowner (Cook 2016a, 2016b, pers. comm.), in the loblolly-longleaf pine mixed stands of the Kepler Lake and Sandylands CMAs, approximately 50 percent (430 ac (174 ha)) and 55 percent (475 ac (192 ha)), respectively, have been planted with longleaf pine beginning in 2001. Using a combination of supplemental funding sources (*e.g.,* Service Private Stewardship Grant, Western Gulf Coastal Plain Prescribed Burning Initiative), the present landowner has completed prescribed burning of hundreds of acres on the CMAs each year since 2000 (except in 2005, 2008, 2009, and 2012). Additionally, midstory (hardwood and shrub) control is achieved in the CMAs by application of herbicide in narrow bands alongside the planted trees instead of broadcast spraying, which limits damage of herbaceous vegetation.

Most of the 59,380 acres (24,030 ha) of timberlands surrounding the CMAs of the Bienville population are managed with intensive silvicultural practices that typically preclude continual, robust herbaceous vegetation growth. Reichling *et al.* (2008, p. 10) did not believe that isolated management areas that were 800 to 1,000 ac (324 to 405 ha) or less in size were sufficient to support viable Louisiana pinesnake populations, and therefore concluded the snakes in the Kepler Lake CMA were likely dependent upon the surrounding habitat. Consequently, Reichling *et al.* (2008, p. 10) felt that it was essential to the conservation of the species to restore and preserve the thousands of hectares of privately owned, upland, xeric habitat that surround the Kepler Lake CMA.

The 5,057.8-ac (2,046.8-ha) Scrappin' Valley EOHA is located at least partially within 11,000 acres (4,452 ha) of privately owned forested land referred to as Scrappin' Valley. That area was managed for game animals for decades (Reid 2016, pers. comm.), and one section (approximately 600 ac (243 ha)) was managed specifically for quail. Prescribed burning was applied only to the 600-ac (243-ha) quail area annually and to another 1,500 ac (607 ha) at less frequent intervals. The remainder of the property was not beneficially managed for Louisiana pinesnake habitat. In 2012, the property was subdivided and sold as three separate properties of 1,900, 1,500, and 7,700 acres (769, 607, and 3,116 ha), respectively.

On the 1,900-ac (769-ha) property from 2013 to spring 2016, hundreds of acres (some acres burned multiple times) of longleaf dominated pine forest occupied by the red-cockaded woodpecker or near red-cockaded woodpecker clusters were prescribed-burned each year; hardwood removal was conducted on 300 ac (121 ha); thinning by removal of loblolly and slash pine trees was conducted throughout the entire property; and 105 ac (42 ha) of longleaf pine restoration (removal of existing trees and planted with long leaf pine) was completed. The landowner is also currently working with The Nature Conservancy toward a perpetual conservation easement on 2,105 ac (852 ha) to protect habitat for the red-cockaded woodpecker and the Louisiana pinesnake.

On the 1,500-ac (607-ha) property in 2015, approximately 250 ac (101 ha) of loblolly pine with dense understory vegetation was harvested, and 200 ac (81 ha) of the area was planted with longleaf pine. The landowner voluntarily agreed to manage the area to promote longleaf pine forest over a 10-year period through a Partners for Fish and Wildlife Program agreement with the Service.

On the 7,700-ac (3,116-ha) property, most of the forest was not burned, so there is a dense midstory. Several hundred acres are comprised of young loblolly pine plantation. In 2014, approximately 400 ac (162 ha) were harvested, and in 2015, approximately 205 ac (83 ha) of longleaf pine were planted. The landowner voluntarily agreed to manage the area to promote longleaf pine forest over a 10-year period through a Partners for Fish and Wildlife Program agreement with the Service. Additionally, approximately 1,000 ac of this property are prescribed burned annually.

Overall, less than 50 percent of the Scrappin' Valley EOHA is being managed beneficially for the Louisiana pinesnake, but more than 50 percent of the area is covered under safe harbor agreements (SHAs) for the red-cockaded woodpecker, which require forest management that is generally beneficial to the Louisiana pinesnake.

Longleaf pine forest improvement and restoration efforts are also currently occurring within the historical range of the Louisiana pinesnake on smaller private properties, especially through programs administered by natural resource agencies such as NRCS, and nonprofit organizations such as The Nature Conservancy (TNC). NRCS has provided assistance with thousands of acres of forest thinning, longleaf pine planting, and prescribed burning (Chevallier 2016, pers.comm.). However, the extent of overlap of

increases in longleaf pine acreage, due to this program, with occupied or potential Louisiana pinesnake habitat (*i.e.,* preferable or suitable soils) is unknown because the specific locations of the projects within the area serviced are private and unavailable to the Service. TNC owns 1,551 ac (628 ha) of land within the Vernon Unit of KNF that is managed for the red-cockaded woodpecker and the Louisiana pinesnake (Jacob 2016, pers. comm.).

The Service and LDWF are currently developing a programmatic candidate conservation agreement with assurances (CCAA) for the Louisiana pinesnake. A CCAA is intended to facilitate the conservation of candidate species by giving non-Federal property owners (enrollees) incentives to implement conservation measures. The incentive to a property owner provided through a CCAA is that the Service will impose no further land-, water-, or resource-use restrictions beyond those agreed to in the CCAA should the species later become listed under the Act. If the species does become listed, the property owner is authorized to take the covered species as long as the level of take is consistent with the level identified and agreed upon in the CCAA. The CCAA policy considers that all CCAAs will provide benefits to covered species through implementation of voluntary conservation measures that are agreed to and implemented by property owners.

The Louisiana pinesnake programmatic CCAA is intended to establish a framework for participation of the Service and LDWF, and enrollees, through specific actions for the protection, conservation, management, and improvement of the status of the Louisiana pinesnake. Initiation of this CCAA will further the conservation of the Louisiana pinesnake on private lands by protecting known populations and additional potential habitat by reducing threats to the species' habitat and survival, restoring degraded potential habitat on preferred and suitable soils, and potentially reintroducing captive-bred snakes to select areas of the restored habitat.

The CCAA is part of an application for an enhancement of survival permit (permit) under section 10(a)(1)(A) of the Act. The permit, which will be held by LDWF, will authorize take of the Louisiana pinesnake during the period of the CCAA. The permitted take will be that resulting from activities covered in the CCAA and the individual cooperative management agreements between LDWF and enrollees in Louisiana who are willing to engage in voluntary conservation actions for the Louisiana pinesnake. Take authorization provided by the permit will be extended to participating enrollees through certificates of inclusion (COI) issued by LDWF.

The Louisiana pinesnake programmatic CCAA has not been finalized, and thus no enrollment has been initiated. The extent of landowner participation and subsequent conservation benefits are yet to be determined; therefore no conservation benefits to the Louisiana pinesnake from the programmatic CCAA are considered in this proposed rule.

Concentrating effort by using the LRSF-Model to guide priorities, LDWF has been approaching landowners in the Louisiana pinesnake's range in Louisiana to recruit them into the Natural Areas Registry Program (Gregory 2013, pers. comm.). Landowners agree to protect the area and its unique natural elements to the best of their abilities, and they can receive, free of charge, an annual ecological check-up on the health of the plants, animals, or habitat of special concern, and preparation of a management plan.

Additional research and survey efforts are being funded by the Texas Comptroller's office as part of the ''Keeping Texas First'' initiative. The research is underway and being conducted by Texas A&M University; research results are expected to provide additional information on the species' habitat requirements in Texas, which may contribute to future conservation efforts. Surveyors are expected to access suitable habitat on private lands that have previously been unavailable.

Effectiveness of Conservation Efforts: In summary, forest management beneficial to the Louisiana pinesnake has occurred across significant portions of most Louisiana pinesnake EOHAs. The significant increases in the acreages of burning and thinning conducted have improved habitat conditions on many Federal lands that support Louisiana pinesnake populations (Rudolph 2008b, pers. comm.), and reduced the threat of habitat loss in those areas. On private land, there has also been habitat restoration and beneficial management, but it has not been as consistent and is generally on a smaller scale (*i.e.,* less than about 3,000 ac (1,214 ha) in the Scrappin' Valley EOHA) than on Federal lands. The Bienville population, which appears to be the most abundant, has only about 1,700 ac (688 ha) of habitat currently managed specifically for the Louisiana pinesnake, and the home range of one Louisiana pinesnake can be as much as 267 ac (108 ha).

There has been no definitive trend of increased trap success in Louisiana pinesnake populations over time (Rudolph *et al.* 2015, p. 33; Pierce 2015, unpub. data). As just discussed, extensive habitat restoration efforts have occurred on Federal lands where the Louisiana pinesnake occurs. Although the threat of habitat loss has been reduced on much of these lands, none of the populations has shown a definitive response to forest management conservation activities. Those Louisiana pinesnake populations are already small, and the species has a low reproductive rate, so recruitment to the population may not be detected for several years. However, it is also possible that increases in snake abundance may not be captured by traps currently in operation because some newly-created suitable habitat may be in areas farther from the current trap locations.

Summary of Factor A

In summary, the loss and degradation of habitat was a significant historical threat, and remains a current threat, to the Louisiana pinesnake. The historical loss of habitat within the longleaf pine ecosystem occupied by Louisiana pinesnakes occurred primarily due to timber harvest and subsequent conversion of pine forests to agriculture, residential development, and managed pine plantations with only intermittent periods of open canopy. This loss of habitat has slowed considerably in recent years, in part due to efforts to restore the longleaf pine ecosystem in the Southeast. In areas occupied by the Louisiana pinesnake on USFS and U.S. Army lands, mixed longleaf and loblolly pine forests are managed beneficially for the species through thinning, and through prescribed burning of thousands of acres of forests every year. However, habitat loss is continuing today on private land due to incompatible forestry practices, conversion to agriculture, and urbanization, which result in increasing habitat fragmentation (see discussion under *Factor E: Other Natural or Manmade Factors Affecting Its Continued Existence*). While the use of prescribed fire for habitat management and more compatible site preparation has seen increased emphasis in recent years, expanded urbanization, fragmentation, and regulatory constraints will continue to restrict the use of fire and cause further habitat degradation (Wear and Greis 2013, p. 509).

Extensive conservation efforts are being implemented that are restoring and maintaining Louisiana pinesnake habitat for the Fort Polk/Vernon, Peason Ridge, Kisatchie, and Angelina populations. Those populations are not

threatened by continuing habitat loss. Portions of occupied habitat of the Scrappin' Valley (approximately 50 percent) and Bienville populations (about 2.8 percent) of the Louisiana pinesnake are also currently being managed beneficially through voluntary agreements. However, future conservation on private lands, which can change ownership and management practices, is uncertain, and the remaining land in the EOHAs with suitable or preferable soils is generally unsuitable habitat because of the current vegetation structure.

Although the threat of habitat loss has been reduced in much of the Louisiana pinesnake's occupied habitat overall, the likely most abundant population has relatively little beneficially managed land, and none of the populations has yet shown a definitive response to forest management conservation activities.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Ongoing take of Louisiana pinesnakes in Louisiana for commercial, recreational, scientific, or educational purposes has not been previously considered a threat (Boundy 2008, pers. comm.). Removal from wild populations for scientific purposes is not expected to increase significantly in the future. Any potential overutilization would be almost exclusively to meet the demand from recreational snake enthusiasts. According to a 2009 report of the United Nations Environment Program—World Conservation Monitoring Centre (UNEP—WCMC 2009, p. 17), captive-bred Louisiana pinesnakes were advertised for sale on four German Web sites, and two U.S. breeders were listed on another Web site. However, current levels of Louisiana pinesnake collection to support the commercial captive-bred snake market have not been quantified. Reichling (2008, pers. comm.) and Vandeventer (2016, pers. comm.) stated that there appears to be very little demand for this species by private collectors; however, there are at least a few Louisiana pinesnake breeders, and the snakes were still featured in advertisements recently for several hundred dollars for one adult (Castellanos 2016, pers. obs.).

Given the restricted distribution, presumed low population sizes, and low reproductive potential of Louisiana pinesnakes, even moderate collecting pressure would negatively affect extant populations of this species. Webb *et al.* (2002, p. 64) concluded that, in long-lived snake species exhibiting low fecundity, the sustained removal of adults from isolated populations would eventually lead to extirpation.

Non-permitted collection of the Louisiana pinesnake is prohibited by State law in Texas and Louisiana, and most areas in Louisiana where extant Louisiana pinesnake populations occur restrict public access or prohibit collection. In addition, general public collection of the Louisiana pinesnake would be difficult (Gregory 2008, pers. comm.) due to the species' secretive nature, semi-fossorial habits, and current rarity.

Previously in Texas, TPWD has allowed captured Louisiana pinesnakes to be removed from the wild by permitted scientific researchers to help supplement the low representation of snakes from Texas populations in the AZA-managed captive breeding program. Currently, LDWF does not permit the removal from the wild of any wild-caught Louisiana pinesnakes to add founders to the AZA-managed captive-breeding program.

Although concern has been expressed that Federal listing may increase the demand for wild-caught animals (McNabb 2014, *in litt.*), based on the best available information, we have no evidence that overutilization for commercial, recreational, scientific, or educational purposes is currently a threat to the Louisiana pinesnake.

Factor C: Disease or Predation

Like many other animals, the Louisiana pinesnake is potentially impacted by native and introduced predators.

Known natural wild predators of pinesnakes (*Pituophis*) include mammals such as shrews, hawks, raccoons, skunks, and red foxes (Ernst and Ernst 2003, p. 284; Yager *et al.* 2006, p. 34). All of these species are common in the range of the Louisiana pinesnake. Several of these mammalian predators may be anthropogenically enhanced; that is, their numbers often increase with human development adjacent to natural areas (Fischer *et al.* 2012, pp. 810–811). Birds, especially hawks, are also known to prey on pinesnakes (Ernst and Ernst 2003, p. 284; Yager *et al.* 2006, p. 34). In one Louisiana pinesnake occurrence record, the snake was described as being ''in combat with hawk,'' presumably a predation attempt by the bird (Young and Vandeventer 1988, p. 204; Pierce 2015, unpub. data). Some snake species prey on other snakes, including pinesnakes. The scarlet snake (*Cemophora coccinea*) has been documented to prey on northern pinesnake eggs (Burger *et al.* 1992, p. 260). This species is found within the range of the Louisiana pinesnake. An eastern coachwhip (*Masticophis flagellum flagellum*), which is an abundant species in the Louisiana pinesnake's range, was observed attempting to predate a juvenile northern pinesnake in North Carolina (Beane 2014, p. 143). Speckled kingsnakes (*Lampropeltis getula holbrooki*) prey on pinesnakes (Ernst and Ernst 2003, p. 279), and one caught in a trap set for the Louisiana pinesnake was observed to have recently consumed another snake (Gregory 2015, pers. comm.).

Pinesnakes also suffer from attacks by domesticated mammals, including dogs and cats (Ernst and Ernst 2003, p. 284). Lyman *et al.* (2007, p. 39) reported an attack on a black pinesnake by a stray domestic dog, which resulted in the snake's death.

Invasive feral hogs are known to inhabit some Louisiana pinesnake EOHAs (Gregory 2016, pers. comm.), including the Catahoula Reintroduction Feasibility EOHA (Nolde 2016, pers. comm.), and are known to prey upon vertebrate animals, including snakes (Wood and Roark 1980, p. 508). They will also consume eggs of ground-nesting birds (Henry 1969, p. 170; Timmons *et al.* 2011, pp. 1–2) and reptiles (Elsey *et al.* 2012, pp. 210–213); however, there is no direct evidence that feral hogs prey on Louisiana pinesnakes or their eggs. Therefore, at this time, feral hogs are not known to be a threat to the Louisiana pinesnake. The Service and USFS are currently engaged in feral hog population control throughout Louisiana and Texas.

Red imported fire ants (*Solenopsis invicta*), an invasive species, have been implicated in trap mortalities of black pinesnakes during field studies (Baxley 2007, p. 17). Red imported fire ants also occur in areas occupied by Louisiana pinesnakes and are potential predators of Louisiana pinesnake eggs and hatchlings (Parris *et al.* 2002, p. 514; Beane 2014, p. 142); they have also been documented predating snake eggs under experimental conditions (Diffie *et al.* 2010, p. 294).

While there are no documented occurrences of successful predation (excessive or otherwise) specifically on Louisiana pinesnakes, predation on pinesnakes has been documented (Burger *et al.* 1992, entire; Baxley 2007, p. 17; Ernst and Ernst 2003, p. 284; Ernst and Ernst 2003, p. 284; Yager *et al.* 2006, p. 34). Even with the assumption that the Louisiana pinesnake is currently subject only to natural, historical types and rates of predation without additional pressure from invasive predators (*e.g.,* feral hogs,

red imported fire ants), the synergistic effect of that predation, together with other known sources of unnatural mortality on the currently reduced size of remaining Louisiana pinesnake populations, constitutes a threat to the species.

Snake fungal disease (SFD) is an emerging disease in certain populations of wild snakes. It has been linked to mortality events for other species, including one juvenile broad-banded watersnake (*Nerodia fasciata confluens* [Blanchard]) in Louisiana (Glorioso *et al.* 2016, p. N5). The causative fungus (*Ophidiomyces ophiodiicola*) (Lorch *et al.* 2015, p. 5; Allender *et al.* 2015, p. 6) and evidence of disease have been documented in one Louisiana pinesnake. Symptoms of SFD (*e.g.,* skin lesions) were found on one Louisiana pinesnake; scale clippings from the snake were analyzed and the causative fungus was positively identified (Lorch *et al.,* in press). However, while SFD is suspected of threatening small, isolated populations of susceptible snake species, we currently have no evidence that SFD is negatively affecting Louisiana pinesnake individuals or populations. We know of no other diseases that are affecting the species, and, therefore, at this time, disease is not considered a threat to the Louisiana pinesnake.

Factor D: The Inadequacy of Existing Regulatory Mechanisms

In Texas, the Louisiana pinesnake is listed as State threatened, and prohibited from unauthorized collection (31 Texas Administrative Code [TAC] sections 65.171–176). As of February 2013, unpermitted killing or removal of native species of reptiles from the wild is prohibited in Louisiana (Louisiana Administrative Code, title 76, part XV, Reptiles and Amphibians, chapter 1, section 101.J.3(f)). Collection or harassment of Louisiana pinesnake is also specifically prohibited on USFS properties in Louisiana (USDA Forest Service 2002, p. 1). The capture, removal, or killing of non-game wildlife from Fort Polk and Peason Ridge (DOD land) is prohibited without a special permit (U.S. Department of the Army 2008, p. 6; U.S. Department of the Army 2013, p. 51). USFS's land and resource management plans (KNF, ANF), the Army's integrated natural resources management plans (INRMPs) (Fort Polk Main Post and Peason Ridge), and the Louisiana pinesnake CCA all require habitat management that is beneficial to the Louisiana pinesnake for the Kisatchie NF, Angelina NF, Fort Polk/Vernon, and Peason Ridge populations (see ''Conservation Efforts to Reduce Habitat Destruction, Modification, or Curtailment of Its Range,'' above). The Service has never been informed of any difficulties in the implementation or enforcement of the existing regulatory mechanisms that protect Louisiana pinesnakes by TPWD, LDWF, or Federal land managers, and no occurrences of noncompliance, including killing of snakes, have been reported to us (see *Factor E* discussion, below).

Its habitat requirements being similar to that of the red-cockaded woodpecker, the Louisiana pinesnake receives indirect protection of its habitat via the protections of the Act provided for the endangered red-cockaded woodpecker, where it co-occurs with the red-cockaded woodpecker on Federal lands.

These existing regulatory mechanisms provide no protection from the threat of Louisiana pinesnake habitat loss and degradation on privately owned lands, including those which contain the Bienville and Scrappin' Valley populations of the Louisiana pinesnake. Private landowners within some occupied habitat of the Scrappin' Valley population have voluntarily committed to agreements with the Service to manage those areas with prescribed burning and to promote the longleaf pine ecosystem for 10 years.

In summary, although existing regulatory mechanisms appear to be adequate to prohibit direct harm to individual Louisiana pinesnakes across their entire range, and offer some protection to habitat on publicly owned land, they offer no protection to the already degraded, fragmented, and declining habitat that exists on private lands.

Factor E: Other Natural or Manmade Factors Affecting Its Continued Existence

The historical loss, degradation, and fragmentation of the longleaf pine ecosystem across the entire historical range of the Louisiana pinesnake have resulted in six natural extant Louisiana pinesnake populations that are isolated and small. Habitat fragmentation and degradation on lands in between extant populations (Rudolph *et al.* 2006, p. 470) have likely reduced the potential for successful dispersal among remnant populations, as well as the potential for natural recolonization of vacant or extirpated habitat patches.

Small, isolated populations resulting from habitat fragmentation are vulnerable to the threats of decreased demographic viability, increased susceptibility of extirpation from stochastic environmental factors (*e.g.,* extreme weather events, epidemic disease), and the potential loss of valuable genetic resources resulting from genetic isolation with subsequent genetic drift, decreases in heterozygosity, and potentially inbreeding depression (Lacy 1987, p. 147). Kwiatkowski *et al.* (2014, pp. 15–18) found that the wild populations of the Louisiana pinesnake had lower heterozygosity and higher inbreeding than what is expected from a randomly breeding population. Low genetic diversity in small, isolated populations has been associated with negative effects on reproduction in snakes (Madsen 1996, p. 116). Recovery of a Louisiana pinesnake population from the existing individuals within the population following a decline is also uncertain because of the species' low reproductive rate (smallest clutch size [three to five] of any North American colubrid snake) (Reichling 1990, p. 221). Additionally, it is extremely unlikely that habitat corridors linking extant populations will be secured and restored; therefore, the loss of any extant population will be permanent without future reintroduction and successful recruitment of captive-bred individuals.

Roads surrounding and traversing the remaining Louisiana pinesnake habitat pose a direct threat to the species. Population viability analyses have shown that extinction probabilities for some snake species may increase due to road mortality (Row *et al.* 2007, p. 117). In an assessment of data from radio-tracked eastern indigo snakes (*Drymarchon corais couperi*), it was found that adult snakes have relatively high survival in conservation core areas, but greatly reduced survival in edges of these areas along highways and in suburbs (Breininger *et al.* 2012, p. 361). In a Texas snake study, an observed deficit of snake captures in traps near roads suggests that a substantial proportion of the total number of snakes may have been eliminated due to road-related mortality (Rudolph *et al.* 1999, p. 130). That study found that populations of large snakes may be depressed by 50 percent or more due to proximity to roads, and measurable impacts may extend up to approximately 0.5 mi (850 m) from roads. During a radio-telemetry study in Louisiana and Texas, 3 of the 15 (20 percent) Louisiana pinesnake deaths documented could be attributed to vehicle mortality (Himes *et al.* 2002, p. 686). Approximately 16 percent (37 of 235) of all documented Louisiana pinesnake occurrences were on roads, and about half of those were dead individuals (Pierce 2015, unpub. data). During Duran's (1998, pp. 6, 34) study on Camp Shelby, Mississippi, 17

percent of the black pinesnakes with transmitters were killed while attempting to cross a road. In a larger study currently being conducted on Camp Shelby, 14 (38 percent) of the 37 pinesnakes found on the road between 2004 to 2012 were found dead, and these 14 individuals represent about 13 percent of all the pinesnakes found on Camp Shelby during that 8-year span (Lyman *et al.* 2012, p. 42). In Louisiana and Texas, areas with relatively large areas of protected suitable habitat and controlled access such as Fort Polk, KNF, and ANF, have several roads located within Louisiana pinesnake occupied habitat, and there have been a total of eight known mortalities due to vehicles in those areas (Pierce 2015, unpub. data).

In addition, Dodd *et al.* (2004, p. 619) determined that roads fragment habitat for wildlife. Clark *et al.* (2010, pp. 1059–1069) studied the impacts of roads on population structure and connectivity in timber rattlesnakes (*Crotalus horridus*). They found that roads interrupted dispersal and negatively affected genetic diversity and gene flow among populations of this large snake, and was likely due to mortality and avoidance of roads (Clark *et al.* 2010, pp. 1059, 1067).

Malicious killing of snakes by humans is a significant issue in snake conservation because snakes arouse fear and resentment from the general public (Bonnet *et al.* 1999, p. 40). Intentional killing of black pinesnakes by humans has been documented (Duran 1998, p. 34; Lyman *et al.* 2008, p. 34). The intentional killing of Louisiana pinesnakes by humans is not unlikely, but because of the species' relatively low abundance and secretive nature, it likely happens very infrequently and, therefore, is not considered a threat at this time.

On many construction project sites, erosion control blankets are used to lessen impacts from weathering, secure newly modified surfaces, and maintain water quality and ecosystem health. However, the commonly used polypropylene mesh netting (also often utilized for bird exclusion) has been documented as being an entanglement hazard for many snake species, causing lacerations and sometimes mortality (Stuart *et al.* 2001, pp. 162–163; Barton and Kinkead 2005, p. 34A; Kapfer and Paloski 2011, p. 1; Zappalorti 2016, p. 19). This netting often takes years to decompose, creating a long-term hazard to snakes, even when the material has been discarded (Stuart *et al.* 2001, p. 163). Although no known instance of injury or death from this netting has been documented for Louisiana pinesnakes, it has been demonstrated to have negative impacts on other terrestrial snake species of all sizes and thus poses a potential threat to the Louisiana pinesnake when used in its habitat.

Exotic plant species degrade habitat for wildlife, and in the Southeast, longleaf pine forest associations are susceptible to invasion by the exotic cogongrass (*Imperata cylindrica*). That plant species may rapidly encroach into areas undergoing habitat restoration, and is very difficult to eradicate once it has become established, requiring aggressive control with herbicides (Yager *et al.* 2010, pp. 229–230). Cogongrass displaces native grasses, greatly reducing foraging areas for some animals, and forms thick mats that restrict movement of ground-dwelling wildlife; it also burns at high temperatures that can kill or injure native seedlings and mature trees (DeBerry and Pashley 2008, p. 74; Alabama Cooperative Extension System 2005, p. 1). Its value as forage for pocket gophers is not known. Currently, cogongrass is limited to only a few locations in Louisiana and Texas, and is not considered a threat to the Louisiana pinesnake. However, cogongrass has significantly invaded States to the east of Louisiana, such as Alabama and Mississippi (Alabama Cooperative Extension System 2005, p. 1–4; USDA NRCS Plant Database 2016, p. 2), where it occurs in pine forests on Camp Shelby (Yager *et al.* 2005, p. 23) potentially impacting the habitat of black pinesnakes found there.

The effects of climate change are predicted to have profound impacts on humans and wildlife in nearly every part of the world (International Panel on Climate Change [IPCC] 2014, p. 6). One downscaled projection for future precipitation change within the historical range of the Louisiana pinesnake varies between increasing and decreasing, but the average change is between 0.1 in (0.254 cm) drier and 1.1 in (2.8 cm) drier from 2020 to 2039 (Pinemap 2016, entire). Precipitation is projected to decrease even more for the 20 years following 2039. Additionally, the average summer temperature in the species' historical range is expected to increase by 2.7–3.5 degrees Fahrenheit (Pinemap 2016, entire). Increasing temperature and decreasing precipitation could potentially affect the pine forest habitat of the Louisiana pinesnake due to drought stress on trees, and the snake itself may be susceptible to injury from higher temperatures or from decreased water availability. However, the Service is not aware of any information that would substantiate those effects or how the Louisiana pinesnake might adapt to those potential environmental stressors.

Effects of native phytophagous (plant-eating) insect species on Louisiana pinesnake habitat may increase due to the effects of climate change. In a study that modeled the effects of the southern pine beetle (*Dendroctonus frontalis*) related to environmental variables, southern pine beetle outbreak risk and subsequent damage to southern pine forests were substantially increased when considered for four separate climate change scenarios (Gan 2004, p. 68). In the openings left in the beetle-damaged pine forests, hardwoods may become the canopy dominants, and invasive vegetation may be more likely to colonize (Waldrop 2010, p. 4; Coleman *et al.* 2008, pp. 1409–1410), both of which can decrease the amount of herbaceous vegetation that the Louisiana pinesnake's primary prey (Baird's pocket gopher) depends upon for food.

The Service considers the effects of increased temperatures, decreased precipitation, and increased insect impacts on the Louisiana pinesnake and its habitat due to climate change to be a potential threat in the future; however, because of the uncertainty of the rate, scale, and location of impacts due to climate effects, climate change is not currently considered a threat to the species.

Conservation Efforts To Reduce Threats Under Factor E

Efforts to reduce Factor E threats would have to address increasing the resiliency of individual populations by increasing abundance and decreasing mortality, or preferably both. Currently, there are ongoing efforts to reduce at least some types of mortality and to study the potential of increasing the number of wild Louisiana pinesnakes via introduction of captive-bred individuals.

As discussed above under *Population Estimates and Status,* efforts to reintroduce Louisiana pinesnakes have been conducted only at the KNF Catahoula District site, where the Louisiana pinesnake is not known to have historically occurred. So far, there have been no attempts to augment existing populations of Louisiana pinesnakes with captive-bred individuals. Reintroduction, with improved success, done in multiple populations where appropriate habitat is available, has the potential to eventually increase the number of individuals and populations, increase genetic heterozygosity, and alleviate presumed inbreeding depression in the populations, making them more

resistant to threats described for Factor E.

As outlined in the CCA, the U.S. Army has committed to avoiding use erosion control blankets, and USFS is committed to trying to locate ATV routes outside of the boundaries of Louisiana pinesnake occupied habitat. Additionally, some improved roads on National Forests are also closed to the public during certain times of the year (*e.g.,* September to February at ANF [U.S. Forest Service 2015, entire]), which should reduce the number of pinesnakes potentially killed by vehicle traffic during those times.

In summary, a variety of natural or manmade factors, alone and in combination with other factors, currently threaten the Louisiana pinesnake. Fire suppression has been considered a primary reason for continuing degradation of the pine forests in Louisiana and Texas. Roads and rights-of-way, and fragmented habitat, isolate populations beyond the dispersal range of the species. Mortality caused by vehicle strikes is a threat because there are many roads bisecting Louisiana pinesnake habitat, and the remaining populations appear to be small and declining. The species' small clutch size may limit its ability to effectively counteract mortality. Other potential threats to Louisiana pinesnakes include SFD, erosion control blankets, insect and invasive vegetation effects on habitat, and malicious killing by humans. Overall, the threats under Factor E may act together and in combination with threats listed above under Factors A through D and increase their severity.

Proposed Determination

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Louisiana pinesnake. Threats to the six known remaining Louisiana pinesnake populations exist primarily from: (1) Historical and continuing habitat loss and fragmentation (Factor A) primarily through land-use changes or degradation caused by fire suppression; and (2) synergistic effects from mortality caused by vehicle strikes and by predators acting on vulnerable, reduced populations (Factor E and Factor C).

Portions of habitat occupied by two Louisiana pinesnake populations on private land are currently being managed beneficially for the species (some through formal agreements with the Service), and conservation efforts on Federal lands, such as KNF and ANF, and U.S. Army lands at Fort Polk and Peason Ridge through a CCA in existence since 2003, have been extensive and successful in restoring suitable Louisiana pinesnake habitat. However, the lack of a definitive positive response by the species' populations indicates that habitat restoration may take much longer than expected to increase snake abundance, especially when they are subjected to negative effects associated with small populations of animals (*i.e.,* reduced heterozygosity, inbreeding depression) and mortality pressure from vehicles and predators.

A captive-breeding population of Louisiana pinesnakes is also being maintained across 18 AZA accredited institutions and 2 non-AZA partner institutions. This captive population, established in 1984, has been managed under an AZA Species Survival Plan (SSP) since 2000. As of March 2016, this captive-breeding population consists of 111 individuals (51 males, 53 females, and 7 unsexed). Since 2010, this population has provided 77 captive-bred Louisiana pinesnakes for release into the wild at the Catahoula Ranger District of the KNF. This reintroduction feasibility effort has shown that at least one of the 77 captive-bred Louisiana pinesnakes has survived for at least 4 years after release in optimal habitat.

The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' We find that the Louisiana pinesnake meets the definition of a threatened species based on the severity and immediacy of threats currently impacting all populations of the species throughout all of its range. The species' overall range has been significantly reduced, populations have apparently been extirpated, and the remaining habitat (on private lands) and populations are threatened by factors acting in combination to reduce the overall viability of the species.

We find that the Louisiana pinesnake does not meet the definition of an endangered species due to the existence of multiple populations within the species' range; the extensive habitat restoration and management efforts to benefit the species ongoing within occupied areas currently being managed by the USFS and U.S. Army, as well as similar efforts ongoing (albeit generally smaller and to a lesser extent) within occupied areas currently being managed on private lands; and reintroduction of captive-bred animals into the wild, which has shown some limited success (see *Catahoula Reintroduction Feasibility EOHA, p. 32*).

Since completion of the CCA in 2003, beneficial forest management activities conducted by USFS and the U.S. Army have been formally dedicated to conservation of the Louisiana pinesnake. Extensive habitat restoration efforts have occurred on USFS and U.S. Army lands where the species occurs, and those populations are no longer threatened by continuing habitat loss. The resulting increases in snake abundance may not be reflected in captures by traps currently in operation because some newly-created suitable habitat may be in areas farther from current trap locations. While it is difficult to show an increase in population size with a species that is so difficult to detect, it is reasonable to assume that these populations will benefit from improved habitat management over time.

The Louisiana pinesnake captive-breeding population provides some capability for population augmentation or re-establishing populations in areas with suitable habitat through the SSP. The goals of the SSP are to: Maintain an assurance colony for wild Louisiana pinesnake populations, preserve or increase genetic heterozygosity into the future, preserve representative genetic integrity of wild populations, and provide individuals as needed for research and repopulation for the conservation of wild populations. While reintroduction as a conservation tool is not universally accepted as effective for all animals, and the results of current reintroduction pilot efforts remain uncertain, the number (77) of captive-bred Louisiana pinesnakes released into the wild since 2010 demonstrates that captive-propagation efforts are successful, and provides the opportunity for reintroduction/augmentation to benefit the conservation of the species.

The Louisiana pinesnake is likely to become endangered in the foreseeable future because the remaining populations are small, isolated, subject to ongoing natural and unnatural mortality pressure, and to date have not shown a definitive positive response to habitat restoration. The species currently has almost no potential for natural recolonization between populations, and multiple significantly affected populations may be unable to recover even with the restoration of appropriate habitat. Half (three) of the known natural extant populations (*i.e.,* Kisatchie, Scrappin' Valley, and Angelina EOHAs) have had no captures in several years and it is likely that they will be considered extirpated in 7 years

or less based on our population determination criteria, unless occurrences are documented in those areas before then.

Future conservation of the two extant populations on private lands, which can change ownership and management practice, is uncertain. Portions of the occupied habitat on these private lands are being managed beneficially for Louisiana pinesnake, but there is no permanent commitment from the current landowners to continue such efforts; the other portions with suitable or preferable soils are generally unsuitable habitat because of the current vegetation structure. The Scrappin' Valley population is at risk of being considered extirpated, as discussed immediately above. The Bienville population is one of the two largest populations; should the ownership of those lands change or the commitment to current habitat management efforts on lands supporting the population cease, it is likely that this large population would decline and could become extirpated within the foreseeable future.

Significant Portion of the Range

Under the Act and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. Because we have determined that the Louisiana pinesnake is threatened throughout all of its range, no portion of its range can be ''significant'' for purposes of the definitions of ''endangered species'' and ''threatened species.'' See the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014).

Conclusion

Therefore, on the basis of the best available scientific and commercial information, we propose to list the Louisiana pinesnake as threatened in accordance with sections 3(20) and 4(a)(1) of the Act. The six known extant populations are all relatively small, and all are subject to one or more of the continuing threats discussed above, making them all vulnerable to extirpation. We find that an endangered species status is not appropriate for the Louisiana pinesnake because while we find the threats to the species to be significant, ongoing, and occurring mostly range-wide, multiple populations continue to occur within the species' range, and all of the populations' occupied habitat or portions of it (including two of the largest populations) are currently being managed to provide more suitable habitat for the species. The two largest populations also have had relatively consistent numbers of detections of individuals in the last 12 years. Captive-propagation efforts have been demonstrated to be successful, and while still unproven at this point, reintroduction pilot efforts provide the opportunity for efforts to re-establish new populations or augment existing populations to benefit the conservation of the species.

Critical Habitat

Section 3(5)(A) of the Act defines critical habitat as: (i) The specific areas within the geographical area occupied by the species, at the time it is listed on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed upon a determination by the Secretary that such areas are essential for the conservation of the species.

Section 4(a)(3) of the Act and implementing regulations (50 CFR 424.12) require that we designate critical habitat at the time a species is determined to be an endangered or threatened species, to the maximum extent prudent and determinable. Our regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist: (1) The species is threatened by taking or other activity and the identification of critical habitat can be expected to increase the degree of threat to the species; or (2) such designation of critical habitat would not be beneficial to the species. As discussed above (see *Factor B* discussion), there is currently no imminent threat of take attributed to collection or vandalism for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In the absence of finding that the designation of critical habitat would increase threats to a species, if there are any benefits to a critical habitat designation, a finding that designation is prudent is warranted. Here, the potential benefits of designation include: (1) Triggering consultation under section 7 of the Act, in new areas for action in which there may be a Federal nexus where it would not otherwise occur because, for example, it is unoccupied; (2) focusing conservation activities on the most essential features and areas; (3) providing educational benefits to State or county governments or private entities; and (4) preventing inadvertent harm to the species. Accordingly, because we have determined that the designation of critical habitat will not likely increase the degree of threat to the species and may provide some measure of benefit, we determine that designation of critical habitat is prudent for the Louisiana pinesnake.

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the species is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist: (i) Information sufficient to perform required analyses of the impacts of the designation is lacking, or (ii) the biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

As discussed above, we have reviewed the available information pertaining to the biological needs of the species and habitat characteristics where this species is located. On the basis of a review of available information, we find that critical habitat for Louisiana pinesnake is not determinable because the specific information sufficient to perform the required analysis of the impacts of the designation is currently lacking, such as information on areas to be proposed for designation and the potential economic impacts associated with designation of these areas. We are in the process of obtaining this information. We will make a determination on critical habitat no later than 1 year following any final listing determination.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies; private organizations; and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective

measures of the Act. Subsection 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for downlisting or delisting, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. If the species is listed, the recovery outline, draft recovery plan, and the final recovery plan would be available on our Web site (*http://www.fws.gov/endangered*), or from our Louisiana Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their ranges may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands. If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Louisiana and Texas would be eligible for Federal funds to implement management actions that promote the protection or recovery of the Louisiana pinesnake. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the Louisiana pinesnake is only proposed for listing under the Act at this time, please let us know if you are interested in participating in conservation efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the U.S. Forest Service and the Department of Defense.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to threatened wildlife. The prohibitions of section 9(a)(1) of the Act, codified at 50 CFR 17.31, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) threatened wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any listed species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, for economic hardship, for zoological exhibition, and for incidental take in connection with otherwise lawful activities. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify, to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. Based on the best available information, the following activities may potentially result in a violation of section 9 of the Act; this list is not comprehensive:

(1) Unauthorized collecting, handling, possessing, selling, delivering, carrying, or transporting of the Louisiana pinesnake, including interstate transportation across State lines and import or export across international boundaries, except for properly documented antique specimens of these taxa at least 100 years old, as defined by section 10(h)(1) of the Act.

(2) Introduction of nonnative animal species that compete with or prey upon the Louisiana pinesnake.

(3) Introduction of invasive plant species that contribute to the degradation of the natural habitat of the Louisiana pinesnake.

(4) Unauthorized destruction or modification of suitable occupied Louisiana pinesnake habitat that results in long-term damage to or alteration of

desirable herbaceous vegetation or the destruction of Baird's pocket gopher burrow systems used as refugia by the Louisiana pinesnake, or that impairs in other ways the species' essential behaviors such as breeding, feeding, or sheltering.

(5) Unauthorized use of insecticides and rodenticides that could impact small mammal prey populations, through either unintended or direct impacts within habitat occupied by Louisiana pinesnakes.

(6) Unauthorized actions that would result in the destruction of eggs or cause mortality or injury to hatchling, juvenile, or adult Louisiana pinesnakes.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Louisiana Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act, need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* and upon request from the Louisiana Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Louisiana Ecological Services Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11 paragraph (h) by adding an entry for ''Pinesnake, Louisiana'' to the List of Endangered and Threatened Wildlife in alphabetical order under REPTILES to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
* * *	* * *	* * *		
REPTILES				
* * *	* * *	* * *		
Pinesnake, Louisiana	*Pituophis ruthveni*	Wherever found	T	[***Federal Register*** *citation of the final rule*]
* * *	* * *	* * *		

Dated: September 26, 2016.

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2016–24113 Filed 10–5–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2016–0031; 4500030113]

RIN 1018–BA79

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Black Warrior Waterdog

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for the Black Warrior waterdog (*Necturus alabamensis*) under the Endangered Species Act (Act). In total, approximately 1,073 river kilometers (669 river miles) in Blount, Cullman, Etowah, Fayette, Jefferson, Lawrence, Marshall, Tuscaloosa, Walker, and Winston Counties, Alabama, fall within the boundaries of the proposed critical habitat designation. We also announce the availability of a draft economic analysis (DEA) of the proposed critical habitat designation. Elsewhere in this issue of the **Federal Register**, we

propose to list the Black Warrior waterdog as an endangered species under the Act.

DATES: We will accept comments received or postmarked on or before December 5, 2016. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by November 21, 2016.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter Docket No. FWS–R4–ES–2016–0031, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R4–ES–2016–0031, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Document availability: The draft economic analysis is available on the Service's Web site at *http://www.fws.gov/Daphne,* on the Federal eRulemaking Portal at *http://www.regulations.gov* under Docket No. FWS–R4–ES–2016–0031, and at the Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

The coordinates or plot points or both from which the maps are generated are included in the administrative record for this proposed rule and are available on the Service's Web site at *http://www.fws.gov/Daphne,* on the Federal eRulemaking Portal at *http://www.regulations.gov* under Docket No. FWS–R4–ES–2016–0031, and at the Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**). Any additional tools or supporting information that we may develop for this critical habitat designation will also be available at the Service's Web site and Field Office identified above, and may also be available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: William Pearson, Field Supervisor, U.S. Fish and Wildlife Service, Alabama Ecological Services Field Office, 1208 Main Street, Daphne, AL 36526; telephone 251–441–5184; or facsimile 251–441–6222. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act (Act), if we determine that any species is an endangered or threatened species we must designate critical habitat, to the maximum extent prudent and determinable. Designations and revisions of critical habitat can only be completed by issuing a rule.

This rule is a proposed rule to designate critical habitat for the Black Warrior waterdog under the Act.

The basis for our action. Section 4(b)(2) of the Act states that the Secretary shall designate critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if she determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless she determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species.

We prepared an economic analysis of the proposed designation of critical habitat. We prepared an analysis of the economic impacts of the proposed critical habitat designation and related factors. We hereby announce the availability of the draft economic analysis (DEA) and seek public review and comment.

We will seek peer review. We are seeking comments from independent specialists to ensure that our critical habitat proposal is based on scientifically sound data and analyses. Because we will consider all comments and information we receive during the comment period, our final designation may differ from this proposal.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned government agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether there are threats to the species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threat outweighs the benefit of designation such that the designation of critical habitat may not be prudent.

(2) Specific information on:

(a) The amount and distribution of Black Warrior waterdog habitat;

(b) What areas, that were occupied at the time of listing (or are currently occupied) and that contain features essential to the conservation of the species, should be included in the designation and why;

(c) Special management considerations or protection that may be needed in critical habitat areas we are proposing, including managing for the potential effects of climate change; and

(d) What areas not occupied at the time of listing are essential for the conservation of the species and why.

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(4) Information on the projected and reasonably likely impacts of climate change on the Black Warrior waterdog and proposed critical habitat.

(5) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation and the benefits of including or excluding areas that exhibit these impacts.

(6) Information on the extent to which the description of economic impacts in the DEA is a reasonable estimate of the likely economic impacts.

(7) The likelihood of adverse social reactions to the designation of critical habitat, as discussed in the associated documents of the DEA, and how the consequences of such reactions, if likely to occur, would relate to the conservation and regulatory benefits of the proposed critical habitat designation.

(8) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better

accommodate public concerns and comments.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

All comments submitted electronically via *http://www.regulations.gov* will be presented on the Web site in their entirety as submitted. For comments submitted via hard copy, we will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* You may request at the top of your document that we withhold personal information such as your street address, phone number, or email address from public review; however, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Previous Federal Actions

All previous Federal actions regarding the Black Warrior waterdog are described in the proposal to list the species as an endangered species under the Act, published elsewhere in this issue of the **Federal Register**.

Background

The Black Warrior waterdog is a species of salamander that inhabits, and is endemic to, streams above the fall line in the Black Warrior River Basin (Basin) in Alabama. The Black Warrior waterdog is a large, aquatic, nocturnal salamander that permanently retains a larval form and external gills throughout its life (Conant and Collins 1998, pp. 419–420). The Black Warrior waterdog inhabits the same areas as the flattened musk turtle (*Sternotherus depressus*), a species listed as threatened under the Act (52 FR 22418; June 11, 1987). According to Mount (1981, p. 23), optimal habitat for the flattened musk turtle consists of ''segment[s] of a free flowing large creek or small river having the following characteristics: (1) Drainage area between 50 and 500 square miles, (2) depth averaging 2 feet, with vegetated shallows alternating with pools at least 3 to 4 feet deep, (3) pools with detectable current, (4) abundance of submerged rocks with crevices, overlapping flat rocks, or accumulations of boulders, (5) abundant molluscan fauna, (6) low silt load and minimal silt deposits, (7) relatively low nutrient content and bacterial count, (8) moderate temperatures (maximum 85 [degrees Fahrenheit (°F)], and (9) minimal pollution by synthetic chemicals and toxic inorganic materials'' (Bailey 2014, p. 1). We find that the optimal habitat for the flattened musk turtle, as described by Mount, reflects the optimal habitat for the Black Warrior waterdog with two differences: the Black Warrior waterdog's prey preference is insect larva instead of molluscan fauna, and it uses leaf packs (leaves that accumulate in streams and form leaf bundles behind branches, rocks, and other objects) as shelter and foraging habitat.

Critical Habitat

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define ''geographical area occupied by the species'' as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical and biological features within an area, we focus on the specific features that support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. For example, an area currently occupied by the species but that was not occupied at the time of listing may be essential to the conservation of the species and may be included in the critical habitat designation. We designate critical habitat in areas outside the geographical area occupied by a species only when a designation limited to its range would be inadequate to ensure the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific and commercial data available. They require our staff, to the extent consistent with the Act and with the use of the best scientific and commercial data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, other unpublished materials, or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) section 9 of the Act's prohibitions on taking any individual of the species, including taking caused by actions that affect habitat. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the designation of critical habitat is not prudent when one or both of the following situations exist:

(1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species; or

(2) designation of critical habitat would not be beneficial to the species. In determining whether a designation would not be beneficial, the factors the Service may consider include, but are not limited to: Whether the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or whether any areas meet the definition of ''critical habitat.''

As discussed under *Factor B* in the proposed listing rule, which is published elsewhere in this issue of the **Federal Register**, there is currently no imminent threat of take attributed to collection or vandalism for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In the absence of finding that the designation of critical habitat would increase threats to a species, we consider whether such designation of critical habitat would not be beneficial to the species. As discussed in our proposed listing rule, we determined that the present or threatened destruction, modification, or curtailment of a species' habitat or range is a threat to the Black Warrior waterdog. We have also identified, in this proposed rule, areas that meet the definition of critical habitat.

Therefore, because we have determined that the designation of critical habitat will not likely increase the degree of threat to the species and would be beneficial, we find that designation of critical habitat is prudent for the Black Warrior waterdog.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the Black Warrior waterdog is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Information sufficient to perform required analyses of the impacts of the designation is lacking, or

(ii) The biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where this species is located. We have determined that this information is sufficient for us to analyze the impacts of designation, and includes sufficient information about the biological needs of the Black Warrior waterdog to allow us to identify areas for inclusion in critical habitat. Therefore, we conclude that critical habitat is determinable for the Black Warrior waterdog.

Physical or Biological Features

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas within the geographical area occupied by the species at the time of listing to designate as critical habitat, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. We define ''physical or biological features'' at 50 CFR 424.02 as: ''The features that support the life-history needs of the species, including but not limited to, water characteristics,

soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.'' These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical, geographical and ecological distributions of a species.

We derive the specific physical or biological features essential for Black Warrior waterdog from studies of this species' habitat, ecology, and life history as described below. We have determined that the following physical or biological features are essential for Black Warrior waterdog.

Space for Individual and Population Growth and for Normal Behavior

The Black Warrior waterdog is found in the Black Warrior Basin above the fall line (rocky habitat with little sand). According to Mount (1981, p. 23), the Black Warrior waterdog's optimal habitat consists of a ''segment of a free flowing large creek or small river having the following characteristics: (1) Drainage area between 50 and 500 square miles, (2) depth averaging two feet, with vegetated shallows alternating with pools at least three to four feet deep, (3) pools with detectable current, (4) abundance of submerged rocks with crevices, overlapping flat rocks, or accumulations of boulders, (5) abundant molluscan fauna, (6) low silt load and minimal silt deposits, (7) relatively low nutrient content and bacterial count, (8) moderate temperatures (maximum 85 °F), and (9) minimal pollution by synthetic chemicals and toxic inorganic materials.'' The Black Warrior waterdog finds refuge under boulders or rocks and in crevices, lays its eggs on the underside of boulders, feeds on insect larva, and has permeable skin.

Because much is unknown about the spatial habitat requirements of the Black Warrior waterdog, we considered the Neuse River waterdog (*Necturus lewisi*), a closely related species that occurs in the North Carolina piedmont plateau region, as a surrogate species. The Neuse River waterdog inhabits similar microhabitat, has similar feeding requirements, and occurs in the Piedmont plateau region. The tributaries of the Neuse River are characterized with gradients similar to the habitat found in the Black Warrior River Basin. According to Ashton (1985, pp. 103–104), adult and juvenile Neuse River waterdogs utilize microhabitats characterized by moderate stream flow and relatively high dissolved oxygen concentrations, which is consistent with other *Necturus* species found in southern States. Studies of the Neuse River waterdog indicate that adult waterdogs utilize areas with large bedrock outcrops, large boulders with sandy-gravel bottoms, and stream banks with rock outcroppings.

We note that although the Gulf Coast waterdog (*Necturus beyeri*) is also found in the Black Warrior Basin, we did not consider the species as a surrogate for the Black Warrior waterdog because it utilizes a different microhabitat; the Gulf Coast waterdog is usually found below the fall line (sandy habitat). Streams utilized by the Gulf Coast waterdog usually have sandy substrate, flow through flatter terrain, and have broader flood plains than the Black Warrior waterdog's habitat.

Therefore, based on the information above, we identify geomorphically stable streams with substrate consisting of clay or bedrock with little sand, and containing abundant rock crevices, rock slabs, and leaf packs to be essential physical or biological features for the Black Warrior waterdog. The connectivity of these stream microhabitats is essential in accommodating growth and other normal behaviors of the Black Warrior waterdog and in promoting gene flow within the species.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

Food

Feeding habits of the Black Warrior waterdog are unknown but are likely similar to the feeding habits of Neuse River waterdog. Both adult and juvenile Neuse River waterdogs appear to be opportunistic feeders. Braswell and Ashton (1985, pp. 22–27) found that larval waterdog diets consist primarily of a variety of aquatic arthropods (*Ostracoda, Copepoda, Isopoda,* and *Amphipoda*) with some insect larvae (*Odonata, Ephemeroptera, Plecoptera, Trichoptera, Diptera,* and *Coleoptera*). The adult waterdog diet was more expansive than the juvenile diet and included aquatic arthropods, other aquatic and terrestrial invertebrates (earthworms, centipedes, beetles, grubs), and aquatic and terrestrial vertebrates (fish and salamanders) (Braswell and Ashton 1985, pp. 13, 24–25).

Since aquatic invertebrates are an important component of the Black Warrior waterdog's diet—specifically, the prey base of aquatic arthropods, insect larvae (*Odonata, Ephemeroptera, Plecoptera, Trichoptera, Diptera,* and *Coleoptera*), aquatic and terrestrial invertebrates, and aquatic and terrestrial vertebrates—it is essential to also take into consideration the aquatic insects' specific habitat requirements. Merrit and Cummins (1996) described caddisfly and mayfly habitat as a wide variety of standing and flowing water habitats, with the greatest diversity being found in rocky-bottom streams with an abundance of oxygen. As a result, they further identify the food sources as a variety of detritus (leaf packs), algae, diatoms, and macrophytes for the aquatic insects.

Water

As little is known about the specific water quality needs of the Black Warrior waterdog, we evaluated and based the water quality parameters on various factors, specifically Mount's description of optimal habitat, Neuse River waterdog literature, prey species requirements (insect larva), Alabama Department of Environmental Management (ADEM) water quality standards, and water quality requirements for currently listed aquatic species found in the Basin, as follows: rush darter (*Etheostoma phytophilum*), Alabama moccasinshell (*Medionidus acutissimus*), dark pigtoe (*Pleurobema furvum*), orangenacre mucket (*Lampsilis perovalis*), ovate clubshell (*Pleurobema perovatum*), triangular kidneyshell (*Ptychobranchus greenii*), upland combshell (*Epioblasma metastriata*), and southern acornshell (*Epioblasma othcaloogensis*).

Appropriate water quality parameters to support the Black Warrior waterdog's primary prey base and other listed species in the Basin include:

- Water that lacks harmful levels of pollutants, including inorganic contaminates such as copper, arsenic, mercury, and cadmium; organic contaminates such as human and animal waste products; endocrine-disrupting chemicals; pesticides; nitrogen, potassium, and phosphorus fertilizers; and petroleum distillates (ADEM 2014, pp. 12–15);

- Water temperature not exceeding 85 °F;
- Dissolved oxygen 5.5 milligrams per liter (mg/L) or greater;
- Turbidity of an average monthly reading of 15 nephelometric turbidity units (NTUs; units to measure sediment discharge) above background readings;
- 115 mg/L of total suspended solids (TSS; measured as mg/L of sediment in water) or less; and
- A specific conductance (ability of water to conduct an electrical current, based on dissolved solids in the water) of no greater than 225 microsiemens (µS) per centimeter at 80 °F (October 10, 2012; 77 FR 61664).

These water quality parameters are very similar to those identified as the primary constituent elements for the rush darter (*Etheostoma phytophilum*) and the Alabama pearlshell (*Margaritifera marrianae*). The Black Warrior waterdog benefits from instream flow with moderate velocity and continuous daily discharge that allows for longitudinal connectivity regimes (the pathway along the entire length of a stream). The benefits are inclusive of both surface runoff and ground water sources and exclusive of flushing flows caused by stormwater runoff.

The Black Warrior waterdog has similar hydrologic requirements as those of the Neuse River waterdog, which are usually found in streams greater than 15 meters (m) (50 feet (ft)) wide and deeper than 100 centimeters (cm) (3 ft), and are not found in streams where water flow ceases under normal summer dry weather conditions (Braswell and Aston 1985, pp. 26–30). However, based on recent environmental deoxyribonucleic acid (eDNA) research, conducted by Godwin (2014, pers. comm.), the Black Warrior waterdog could be utilizing streams as narrow as 4 m (13 ft) wide.

The quality of the chemical and physical environment of the streams in the upper Black Warrior River Basin is essential to the survival of the Black Warrior waterdog. Optimal water quality lacks harmful levels of pollutants, including inorganic contaminates such as copper, arsenic, mercury, and cadmium; organic contaminates such as human and animal waste products; endocrine-disrupting chemicals; pesticides; nitrogen, potassium, and phosphorus fertilizers; and petroleum distillates (ADEM 2014, pp. 13–15). Factors that can potentially alter water quality include droughts and periods of low seasonal flow, precipitation events, nonpoint source runoff, human activities within the watershed, random spills (oil, chemicals, pesticides, fertilizer, etc.), and unregulated stormwater discharge events. A decrease in water quality and instream flow would correspondingly cause a decline in the major food species for the Black Warrior waterdog. Excessive high water flows can wash away or cover (with sediment) leaf packs that are essential for juvenile and adult waterdog foraging and feeding.

Natural variations of instream flows maintain the stream bottom substrates, providing oxygen and other attributes to various invertebrate life stages. Sedimentation contributes to turbidity of the water and has been shown to reduce photosynthesis in aquatic plants, suffocate aquatic insects, smother aquatic eggs, clog gills, and fill in essential interstitial spaces used by aquatic organisms for spawning and foraging. Sedimentation has been shown to wear away and suffocate periphyton (organisms that live attached to objects underwater) and disrupt aquatic insect communities (Waters 1995, pp. 53–86; Knight and Welch 2004, pp. 132–135).

Therefore, based on the information above, we identify medium to larger streams (typically 4 m (13 ft) wide or greater), containing hard substrate (clay or bedrock with little sand) and abundant rock crevices and rock slabs; cool, clean, flowing water having a dissolved oxygen level of 5.5 mg/L or greater; moderate water velocity; aquatic macroinvertabrate prey items; and leaf packs to be essential physical or biological features for the Black Warrior waterdog.

Cover or Shelter

Preferred substrates for the Black Warrior waterdog are dominated by clay or bedrock with little sand, and also contain abundant rock crevices and rock slabs for retreats (shelter) and areas for egg laying. Based on capture data, the Black Warrior waterdog utilizes leaf pack for shelter from predators and as foraging areas for prey species. We identify hard bottom substrate with a combination of boulders, rock slabs, and rock outcrops for shelter and reproduction and leaf packs to be essential physical and biological features for the Black Warrior waterdog.

Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

Little is known about the specific requirements of Black Warrior waterdog's reproduction. Based on Neuse River waterdog research, breeding sites are large bedrock outcrops or large boulders with sand and gravel beneath them (Ashton 1985, p. 95). Data collected from the Cincinnati Zoo show that the Black Warrior waterdog deposits eggs under rock slabs or in rock crevices, and the female guards the eggs. Juvenile Black Warrior waterdogs are often found in leaf packs in the stream.

Sedimentation can be destructive to Black Warrior waterdogs and their habitat when it contains toxicants and is excessive. Bailey (2000, p. 2) reported that Black Warrior waterdogs are virtually in constant contact with the substrate and; therefore, also with any toxic chemicals present. He also reported that juveniles and adults are impacted by the exposure. Further, excessive sedimentation of the crevices and leaf packs removes foraging, feeding, breeding, and retreat areas for the Black Warrior waterdog (Laschet 2014, pers. obs.).

Therefore, based on the information above, we identify medium to larger streams (4 m wide or greater), with hard substrate (clay or bedrock with little sand, also containing abundant rock crevices and rock slabs) and moderate water velocity; aquatic macroinvertabrate prey items; leaf packs; with adequate water, as defined above, quality to be essential physical and biological features for the Black Warrior waterdog.

Habitats Protected From Disturbance or Representative of the Historical Geographical and Ecological Distributions of the Species

Currently, there are no areas that are undisturbed or that are representative of the historical geographical and ecological distribution of the species that the Black Warrior waterdog typically inhabits. The Bankhead National Forest is an area that can reveal a glimpse of a representative of the historic geographical and ecological features of the species' habitat, and is currently considered the stronghold of the species. Streams in this area typically consisted of geomorphically stable streams with substrate consisting of clay or bedrock with little sand, and containing abundant rock crevices and rock slabs. These streams also contain cool, clean, flowing water having a dissolved oxygen levels of 5.5 mg/L or higher; moderate water velocity; aquatic macroinvertabrate prey items; leaf packs; and adequate water quality (ADEM 2010, pp. 1–3).

Therefore, based on the habitat found on Bankhead National Forest, we identify medium to larger streams (4 m (13 ft) wide or greater) with hard substrate (clay or bedrock with little sand, also containing abundant rock crevices and rock slabs) to be essential physical and biological features for the Black Warrior waterdog.

In summary, based on the information described above we identify the physical or biological features essential to the conservation of the Black Warrior waterdog consists of a riverine system with habitat to support all life-history stages of the Black Warrior waterdog, which consists of the following components:

1. Geomorphically stable, medium to large streams (typically 4 m (13 ft) wide or greater) with:

a. Substrate consisting of clay or bedrock with little sand, and containing abundant rock crevices, rock slabs, and leaf packs;

b. Moderate water velocity; and

c. Prey base of aquatic macroinvertebrates.

2. Water that lacks harmful levels of pollutants, including inorganic contaminants such as copper, arsenic, mercury, and cadmium; organic contaminates such as human and animal waste products; endocrine-disrupting chemicals; pesticides; nitrogen, potassium, and phosphorus fertilizers; and petroleum distillates.

3. Appropriate water quality parameters to support Black Warrior waterdog and primary prey base, including:

a. Water temperature not exceeding 85 °F;

b. Dissolved oxygen 5.5 mg/L or greater;

c. Turbidity of an average monthly reading of 15 NTUs above background readings;

d. 115 mg/L of total suspended solids or less; and

e. A specific conductance of no greater than 225 µS per centimeter at 80 °F.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection.

The features essential to the conservation of the Black Warrior waterdog may require special management considerations or protections to reduce the following threats: (1) Urbanization activities and inadequate stormwater management (such as stream channel modification for flood control or gravel extraction) that could cause an increase in bank erosion; (2) significant changes in the existing flow regime within the streams due to water diversion or withdrawal; (3) significant alteration of water quality; (4) significant alteration in quantity of groundwater, prevention of water percolating into the aquifer recharge zone, and alteration of spring discharge sites; (5) significant changes in stream bed material composition and quality due to changes in stream flow characteristics, construction projects, and maintenance activities; (6) off-road vehicle use; (7) sewer, gas, and water easements; (8) bridge construction; (9) culvert and pipe installation; and (10) other watershed and floodplain disturbances that release sediments or nutrients into the water.

Management activities that could ameliorate these threats include, but are not limited to: Use of best management practices (BMPs) designed to reduce sedimentation, erosion, and bank side destruction; select harvest of trees along banks, and leaving 50 percent canopy cover (of deciduous trees) along banks; moderation of surface and ground water withdrawals to maintain natural flow regimes; increased use of stormwater management and reduction of stormwater flows into the systems; preservation of headwater springs, and spring runs; regulation of off-road vehicle use; and reduction of other watershed and floodplain disturbances that release sediments, pollutants, or nutrients into the water.

In summary, we find that the occupied areas we are proposing to designate as critical habitat for the Black Warrior waterdog contain the physical or biological features that are essential to the conservation of the species and that may require special management considerations or protection. Special management considerations or protection may be required of the Federal action agency to eliminate, or to reduce to negligible levels, the threats affecting the physical and biological features of each unit. The major threats to the Black Warrior waterdog are sedimentation (loss of habitat), water quality (nutrients, turbidity and toxins), and fragmentation from impoundments.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we used the best scientific data available to designate critical habitat. We reviewed available information pertaining to the habitat requirements of the species and surrogates. Based on our review, we are proposing to designate critical habitat in areas within the geographical area occupied by the species at the time of listing (in this case, currently occupied). In accordance with the Act and its implementing regulation at 50 CFR 424.12, we also considered whether designating additional areas—outside those currently occupied—are essential for the conservation of the species. As a result, we also are proposing to designate specific areas outside the geographical area occupied by the Black Warrior waterdog at the time of listing that are within the historical range of the species, but are currently unoccupied, because we have determined that such areas are essential for the conservation of the species.

Areas Occupied at the Time of Listing

For the purpose of proposing critical habitat for the Black Warrior waterdog, we defined the geographical area currently occupied by the species as required by section 3(5)(A)(i) of the Act. We used information from surveys and reports prepared by the Alabama Department of Conservation and Natural Resources, Alabama Geological Survey, Alabama Natural Heritage Program, Auburn University, Alabama Power Company, the U.S. Forest Service, the Natural Resources Conservation Service, and the Service to identify the specific locations occupied by the Black Warrior waterdog. Currently, occupied habitat for the species is isolated and limited to four units. Within these four units, the species is located within seven tributaries in the Black Warrior River Basin. Three of the tributaries are on Bankhead National Forest (Winston County) and include Sipsey Fork, Brushy Creek, and Rush Creek. The other four tributaries are Locust Fork; Gurley Creek, which feeds into Locust Fork (Blount and Jefferson Counties); Blackwater/Browns Creek in Winston County; and Yellow Creek in Tuscaloosa County (Godwin 2014). We have determined that these four units (which include all seven tributaries)—Sipsey Fork, Locust Fork, Browns Creek, and Yellow Creek—meet the criteria for designation as critical habitat. As discussed below, some of these units contain all of the identified elements of physical or biological features and support multiple life-history processes. Some units contain only some elements of the physical or biological features necessary to support the Black Warrior waterdog's particular use of that habitat.

Areas Not Occupied at the Time of Listing

To include areas not occupied by the species at the time of listing in our critical habitat designation, we must demonstrate that these areas are essential to the conservation of the subspecies. To determine if these areas are essential for the conservation of the Black Warrior waterdog, we considered: (1) The importance of the stream to the

overall status of the species and the contribution to the future recovery of the Black Warrior waterdog; (2) whether the area could be restored to contain the necessary habitat to support the Black Warrior waterdog; (3) whether the site provides connectivity between occupied sites for genetic exchange; and (4) whether a population of the species could potentially be reestablished in the area. Lye Branch, Lake Tuscaloosa, Lost Creek, and Mulberry Fork meet these criteria. These areas were formerly occupied by the Black Warrior waterdog and are important in its future recovery, still contain suitable habitat for the species, and can support reestablished populations because they formerly supported the species and continue to support the flattened musk turtle, which has similar habitat requirements as the Black Warrior waterdog. In addition, the Lye Branch unit occurs below the fall line for the Basin, which is a unique location for the Black Warrior waterdog. Due to their separation from the other units, these units have the potential to provide genetic material essential to the recovery of the waterdog.

Mapping Black Warrior Waterdog Critical Habitat

In identifying proposed critical habitat units for the Black Warrior waterdog, we proceeded through a multi-step process. We obtained and reviewed historical records for the Black Warrior waterdog's distribution from Bankhead National Forest and Alabama Natural Heritage, as well as both published and unpublished documentation from our files. Once the historical range was determined, we looked at whether the physical and biological features were present at these historical sites. Then, we reviewed surveys conducted over the last 8 years, including surveys currently being undertaken. We conducted present and absent surveys of known and historical sites and sampled and observed the habitat. Since the Black Warrior waterdog is difficult to detect and capture, we contracted with Alabama Natural Heritage and Auburn University to conduct sampling surveys including the use of eDNA. With the survey results, we confirmed the Black Warrior waterdog's distribution in the Black Warrior River Basin. We determined occupied areas with data collected from surveys conducted over the last 8 years to present. We considered areas that do not have recent capture or sighting data, but that do have historical records prior to the mid-1990s, to be unoccupied by the species.

Our approach to delineating critical habitat units was applied in the following manner:

(1) We overlaid Black Warrior waterdog locations into a GIS database. This provided us with the ability to examine slope, elevation, geologic type, hydrologic factors, vegetation community, and topographic features. These data points verified the previously recorded elevation ranges for Black Warrior waterdog.

(2) In addition to the GIS layers listed above, we then excluded impoundments and dams as barriers for the species, as described in Physical or Biological Features, above.

(3) We then drew critical habitat boundaries that captured the locations as discussed above. The proposed critical habitat designation was then mapped using Projected Coordinate System, NAD 1983 UTM Zone 16N with a Projection of Transverse Mercator.

The proposed critical habitat designation is defined by the maps, as modified by any accompanying regulatory text, presented at the end of this document in the Proposed Regulation Promulgation section. We include more detailed information on the boundaries of the proposed critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *http://www.regulations.gov* at Docket No. FWS–R4–ES–2016–0031, on the Service's Web site at *http://www.fws.gov/daphne/,* and at the field office responsible for the designation (see **FOR FURTHER INFORMATION CONTACT**, above).

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the Black Warrior waterdog. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

Proposed Critical Habitat Designation

We are proposing to designate approximately 1,073 river kilometers (669 river miles) in eight units as critical habitat for the Black Warrior waterdog. The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for the Black Warrior waterdog. The areas we propose as critical habitat are:

(1) Lye Branch: approximately 16 river kilometers (rkm) (10 river miles (rmi)) of stream and river habitat. The unit consists of the headwaters of Lye Branch to the confluence of Big Sandy Creek.

(2) Lake Tuscaloosa: approximately 108 rkm (67 rmi) of stream and river habitat. The unit consists of the headwaters of North River to Tuscaloosa Lake, and from the headwaters of Carroll Creek to Tuscaloosa Lake.

(3) Yellow Creek: approximately 30 rkm (19 rmi) of stream and river habitat. This unit is from the headwaters of Yellow Creek to Holt Lake.

(4) Lost Creek: approximately 93 rkm (58 rmi) of stream and river habitat. This unit is from the headwaters of Lost Creek to Bankhead Lake.

(5) Locust Fork: approximately 391 rkm (243 rmi) of stream and river habitat. This unit is from the headwaters of Locust Fork to Bankhead Lake, from the headwaters of Slab Creek to the confluence of Locust Fork, from the headwaters of Blackburn Fork to the confluence of Locust Fork, and from the headwaters of Gurley Creek to the confluence of Locust Fork.

(6) Mulberry Fork: approximately 183 rkm (114 rmi) of stream and river habitat. This unit consists of the headwaters of Mulberry Fork to Bankhead Lake, and from Little Blackwater Creek to the confluence of Blackwater Creek.

(7) Blackwater Creek: approximately 128 rkm (80 rmi) of stream and river habitat. This unit consists of the headwaters of Blackwater Creek to the confluence of Mulberry Fork, from the headwaters of Brown Creek to the confluence of Blackwater Creek.

(8) Sipsey Fork: approximately 124 rkm (78 rmi) of stream and river habitat. The unit consists of the headwaters of Sipsey Fork to Lewis Smith Lake, from the headwaters of Brushy Creek to Lewis Smith Lake, from the headwaters of Rush Creek to the confluence of Brushy Creek, and from the headwaters of Capsey Creek to the confluence of Brushy Creek.

All of the areas proposed for designation as critical habitat for the Black Warrior waterdog include stream and river channels within the normal high water line.

Table 1 shows the occupancy status of each proposed unit and proposed units that overlap with existing critical habitat units for other federally listed species.

TABLE 1—OCCUPANCY OF BLACK WARRIOR WATERDOG BY PROPOSED CRITICAL HABITAT UNITS AND EXISTING OVERLAPPING CRITICAL HABITAT DESIGNATION FOR FEDERALLY LISTED SPECIES

Unit	Location	Occupied	Private ownership rkm/rmi	Federal ownership rkm/rmi	Existing critical habitat rkm/rmi	Total length rkm/rmi
1	Lye Branch	No	16/10			16/10
2	Lake Tuscaloosa	No	108/67		* 61/38	108/67
3	Yellow Creek	Yes	30/19			30/19
4	Lost Creek	No	93/58			93/58
5	Locust Fork	Yes	391/243		** 101/63	391/243
6	Mulberry Fork	No	183/114			183/114
7	Blackwater Creek	Yes	128/80			128/80
8	Sipsey Fork	Yes	11/7	113/71	*** 103/64	124/78
	TOTALS		960/598	113/71	265/165	1,073/669

* Alabama moccasinshell *(Medionidus acutissimus),* dark pigtoe *(Pleurobema furvum),* orangenacre mucket *(Lampsilis perovalis),* ovate clubshell *(Pleurobema perovatum),* triangular kidneyshell *(Ptychobranchus greenii).*

** Alabama moccasinshell, dark pigtoe, orangenacre mucket, ovate clubshell, upland combshell *(Epioblasma metastriata),* triangular kidneyshell.

*** Alabama moccasinshell, dark pigtoe, orangenacre mucket, ovate clubshell, southern acornshell *(Epioblasma othcaloogensis),* triangular kidneyshell.

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for the Black Warrior waterdog, below. All units are within private ownership, except Unit 8, which also includes Federal ownership.

Unit 1: Lye Branch, Tuscaloosa County

Unit 1 includes 16 rkm (10 rmi) of stream and river habitat consisting of the headwaters of Lye Branch to the confluence of Big Sandy Creek, and is below the fall line. This area is not occupied at the time of listing, but is considered essential for the conservation of the species. Based on a literature review by Bailey (2000, p. 1), specimens were historically collected from this area. This location is the only historical site below the fall line, which makes it unique for the species. If any waterdogs still persist in this area, the genetic material would be essential in the recovery of the Black Warrior waterdog. Lye Branch contains leaf litter and instream flow with moderate velocity and continuous daily discharge that allows for a longitudinal connectivity regime. The instream flow consists of both surface runoff and ground water sources, exclusive of flushing flows caused by stormwater runoff, that are essential for the Black Warrior waterdog in that it provides shelter, breeding, and foraging habitat that would allow for reintroduction and recovery activities for the Black Warrior waterdog.

Unit 2: Lake Tuscaloosa, Fayette and Tuscaloosa Counties, Alabama

Unit 2 includes 108 rkm (67 rmi) of stream and river habitat. The unit consists of the headwaters of North River to Tuscaloosa Lake, and from the headwaters of Carroll Creek to Tuscaloosa Lake. This area is not occupied at the time of listing, but is considered essential for the conservation of the species. Based on a literature review by Bailey (2000, p. 1), specimens were historically collected from this area. North River and Carroll Creek contain abundant rock crevices and rock slabs, leaf litter, and instream flow with moderate velocity and continuous daily discharge that allows for a longitudinal connectivity regime consisting of both surface runoff and ground water sources, exclusive of flushing flows caused by stormwater runoff, that are essential for the Black Warrior waterdog. This unit would provide habitat for reintroduction and recovery activities of the Black Warrior waterdog.

Unit 3: Yellow Creek, Tuscaloosa County, Alabama

Unit 3 includes 30 rkm (19 rmi) of stream and river habitat. The unit consists of the headwaters of Yellow Creek to Holt Lake. This area is occupied at the time of listing (*i.e.,* currently occupied). Godwin (2016, pers. comm.) reported a capture of a Black Warrior waterdog in this area. This area contains the following physical or biological features that are essential for the Black Warrior waterdog: Abundant rock crevices and rock slabs, leaf litter, and instream flow with moderate velocity and continuous daily discharge that allows for a longitudinal connectivity regime inclusive of both surface runoff and ground water sources and exclusive of flushing flows caused by stormwater runoff.

Threats to the physical and biological features in proposed Unit 3 that may require special management considerations or protection include:

- Agriculture and silviculture activities, and urbanization activities, that could result in increased bank erosion;
- Significant changes in the existing flow regime due to inadequate stormwater management, water diversion, or water withdrawal;
- Significant alteration of water quality; and
- Significant changes in stream bed material composition and quality as of result of construction projects and maintenance activities; off-road vehicle use; sewer, gas, and water easements; bridge and road construction and maintenance; culvert and pipe installation; and other watershed and floodplain disturbances that release sediments or nutrients into the water.

Unit 4: Lost Creek, Walker County, Alabama

Unit 4 includes 93 rkm (58 rmi) of stream and river habitat. The unit consists of headwaters of Lost Creek downstream to Bankhead Lake. This

area is unoccupied at the time of listing, but is considered essential for the conservation of the species. Based on a literature review by Bailey (2000, p. 1), Black Warrior waterdogs were historically captured in this area. This area contains abundant rock crevices and rock slabs, leaf litter, and instream flow with moderate velocity and continuous daily discharge that allows for longitudinal connectivity regime consisting of both surface runoff and ground water sources, exclusive of flushing flows caused by stormwater runoff, that are essential for the Black Warrior waterdog. It would provide habitat for reintroduction and recovery activities for the Black Warrior waterdog.

Unit 5: Locust Fork, Blount, Etowah, Jefferson, and Marshall Counties, Alabama

Unit 5 includes 391 rkm (243 rmi) of stream and river habitat. The unit consists of the headwaters of Locust Fork to Bankhead Lake, from the headwaters of Slab Creek to the confluence of Locust Fork, from the headwaters of Blackburn Fork to the confluence of Locust Fork, and from the headwaters of Gurley Creek to the confluence of Locust Fork. This area is occupied at the time of listing (*i.e.,* currently occupied). Based on a literature review by Bailey (2000, p. 1), Black Warrior waterdog specimens have been collected from the Locust Fork area. This area contains the following physical or biological features: abundant rock crevices and rock slabs, leaf litter, and instream flow with moderate velocity and continuous daily discharge that allows for a longitudinal connectivity regime consisting of both surface runoff and ground water sources, exclusive of flushing flows caused by stormwater runoff, that are essential for the Black Warrior waterdog.

Threats to the physical and biological features in proposed Unit 5 that may require special management considerations or protection include:

- Agriculture and silviculture activities, and urbanization activities, that could result in increased bank erosion;
- Significant changes in the existing flow regime due to inadequate stormwater management, water diversion, or water withdrawal;
- Significant alteration of water quality; and
- Significant changes in stream bed material composition and quality as of result of construction projects and maintenance activities; off-road vehicle use; sewer, gas, and water easements; bridge and road construction and maintenance; culvert and pipe installation; and other watershed and floodplain disturbances that release sediments or nutrients into the water.

Unit 6: Mulberry Fork, Blount, Cullman, Marshall, and Walker Counties, Alabama

Unit 6 includes 183 rkm (114 rmi) of stream and river habitat consisting of the headwaters of Mulberry Fork to Bankhead Lake, and from Little Blackwater Creek to the confluence of Blackwater Creek. This area is not occupied at the time of listing, but is considered essential for the conservation of the species. Based on a literature review by Bailey (2000, p. 1), Black Warrior waterdog specimens were historically collected here. This area contains abundant rock crevices and rock slabs, leaf litter, and instream flow with moderate velocity and continuous daily discharge that allows for longitudinal connectivity regime consisting of both surface runoff and ground water sources, exclusive of flushing flows caused by stormwater runoff, that are essential for the Black Warrior waterdog. This unit would provide habitat for reintroduction and recovery activities of the Black Warrior waterdog.

Unit 7: Blackwater Creek, Walker and Winston Counties, Alabama

Unit 7 includes 128 rkm (80 rmi) of stream and river habitat. The unit consists of the headwaters of Blackwater Creek to the confluence of Mulberry Fork, and from the headwaters of Brown Creek to the confluence of Blackwater Creek. This area is occupied at the time of listing based on a literature review by Bailey (2000, p. 1). Godwin (2014, pers. comm.) reported that Black Warrior waterdogs were still present based on eDNA results. This area contains the following physical or biological features: abundant rock crevices and rock slabs, leaf litter, and instream flow with moderate velocity and continuous daily discharge that allows for longitudinal connectivity regime consisting of both surface runoff and ground water sources, exclusive of flushing flows caused by stormwater runoff, that are essential for the Black Warrior waterdog.

Threats to the physical and biological features in proposed Unit 7 that may require special management considerations or protection include:

- Agriculture and silviculture activities, and urbanization activities, that could result in increased bank erosion;
- Significant changes in the existing flow regime due to inadequate stormwater management, water diversion, or water withdrawal;
- Significant alteration of water quality; and
- Significant changes in stream bed material composition and quality as of result of construction projects and maintenance activities; off-road vehicle use; sewer, gas, and water easements; bridge and road construction and maintenance; culvert and pipe installation; and other watershed and floodplain disturbances that release sediments or nutrients into the water.

Unit 8: Sipsey Fork, Lawrence and Winston Counties, Alabama

Unit 8 includes 124 rkm (78 rmi) of stream and river habitat. The unit consists of the headwaters of Sipsey Fork to Lewis Smith Lake, from the headwaters of Brushy Creek Lewis Smith Lake, from the headwaters of Rush Creek to the confluence of Brushy Creek, and from the headwaters of Capsey Creek to the confluence of Brushy Creek. This area falls within the boundary of Bankhead National Forest, although some areas are private inholdings.

This area is occupied at the time of listing, based on recent captures (Godwin 2016, pers. comm.). This area contains the following physical or biological features: abundant rock crevices and rock slabs, leaf litter, and instream flow with moderate velocity and continuous daily discharge that allows for longitudinal connectivity regime consisting of both surface runoff and ground water sources, exclusive of flushing flows caused by stormwater runoff, that are essential for the Black Warrior waterdog.

Threats to the physical and biological features in proposed Unit 8 that may require special management considerations or protection include:

- Agriculture and silviculture activities, and urbanization activities, that could result in increased bank erosion;
- Significant changes in the existing flow regime due to inadequate stormwater management, water diversion, or water withdrawal;
- Significant alteration of water quality; and
- Significant changes in stream bed material composition and quality as of result of construction projects and maintenance activities; off-road vehicle use; sewer, gas, and water easements; bridge and road construction and maintenance; culvert and pipe installation; and other watershed and

floodplain disturbances that release sediments or nutrients into the water.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

On February 11, 2016 (81 FR 7214), we published a final rule setting forth a new definition of destruction or adverse modification, which became effective on March 14, 2016. ''Destruction or adverse modification'' means a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally funded or authorized, do not require section 7 consultation.

As a result of section 7 consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies sometimes may need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Application of the ''Adverse Modification'' Standard

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation. Activities that may affect critical habitat, when carried out, funded, or authorized by a Federal agency, should result in consultation for the Black Warrior waterdog. These activities include, but are not limited to:

(1) Actions that would significantly alter water chemistry or temperature. Such activities could include, but are not limited to, release of chemicals, biological pollutants, or heated effluents into the surface water or connected groundwater at a point source or by dispersed release (non-point source). These activities could alter water conditions to levels that are beyond the tolerances of the species' prey items and result in direct or cumulative adverse effects to the Black Warrior waterdog and its lifecycle.

(2) Actions that would significantly increase sediment deposition within the stream channel. Such activities could include, but are not limited to, excessive sedimentation from livestock grazing, road construction, channel alteration, timber harvest, off-road vehicle use, and other watershed and floodplain disturbances. These activities could eliminate or reduce the habitat necessary for the growth and reproduction of the Black Warrior waterdog by increasing the sediment deposition to levels that would adversely affect its ability to complete its lifecycle.

(3) Actions that would significantly alter channel morphology or geometry. Such activities could include, but are not limited to, channelization, impoundment, road and bridge construction, mining, dredging, and destruction of riparian vegetation. These activities may lead to changes in water flows and levels that would degrade or eliminate the Black Warrior waterdog and/or its habitat. These actions can also lead to increased sedimentation and degradation in water quality to levels that are beyond the tolerances of the Black Warrior waterdog or its prey items.

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that: ''The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan [INRMP] prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a

benefit to the species for which critical habitat is proposed for designation.'' There are no Department of Defense lands with a completed INRMP within the proposed critical habitat designation.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if she determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless she determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute, as well as the legislative history, is clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor. In this proposed rule, we have not considered any areas for exclusion from critical habitat.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. To assess the probable economic impacts of a designation, we must first evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. We then must evaluate the impacts that a specific critical habitat designation may have on restricting or modifying specific land uses or activities for the benefit of the species and its habitat within the areas proposed. We then identify which conservation efforts may be the result of the species being listed under the Act versus those attributed solely to the designation of critical habitat for this particular species. The probable economic impact of a proposed critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.'' The ''without critical habitat'' scenario represents the baseline for the analysis, which includes the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat (*e.g.,* under the Federal listing as well as other Federal, State, and local regulations). The baseline, therefore, represents the costs of all efforts attributable to the listing of the species under the Act (*i.e.,* conservation of the species and its habitat incurred regardless of whether critical habitat is designated). The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts would not be expected without the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs. These are the costs we use when evaluating the benefits of inclusion and exclusion of particular areas from the final designation of critical habitat should we choose to conduct an optional 4(b)(2) exclusion analysis.

For this designation, we developed an incremental effects memorandum (IEM) considering the probable incremental economic impacts that may result from this proposed designation of critical habitat. The information contained in our IEM was then used to develop a screening analysis of the probable effects of the designation of critical habitat for the Black Warrior waterdog and draft Waterdog Screening Memorandum, dated June 30, 2015. The purpose of the screening analysis is to filter out the geographic areas in which the critical habitat designation is unlikely to result in probable incremental economic impacts. In particular, the screening analysis considers baseline costs (*i.e.,* absent critical habitat designation) and includes probable economic impacts where land and water use may be subject to conservation plans, land management plans, best management practices, or regulations that protect the habitat area as a result of the Federal listing status of the species. The screening analysis filters out particular areas of critical habitat that are already subject to such protections and are, therefore, unlikely to incur incremental economic impacts. The screening analysis also assesses whether units are unoccupied by the species and may require additional management or conservation efforts as a result of the critical habitat designation for the species which may incur incremental economic impacts. This screening analysis, combined with the information contained in our IEM, constitutes our draft economic analysis of the proposed critical habitat designation for the Black Warrior waterdog and is summarized in the narrative below.

Executive Orders (E.O.) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with these requirements, our effects analysis may take into consideration impacts to both directly and indirectly impacted entities, where practicable and reasonable. As part of our screening analysis, we considered the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation. First we identified, in the draft Waterdog Screening Memorandum, probable incremental economic impacts associated with the following categories of activities: (1) Federal lands management (U.S. Forest Service, U.S. Bureau of Reclamation); (2) roadway and bridge construction; (3) agriculture; (4) grazing; (5) conservation/restoration; (6) instream dams and diversions; (7) storage and distribution of chemical pollutants; (8) dredging; (9) commercial or residential development; (10) timber harvest; (11) recreation (including sport fishing and sportfish stocking, off-road vehicle activity); (12) mining; (13) in-water construction; (14) utilities; (15) water quality; and (16) water quanity/supply. We considered each industry or category individually. Additionally, we considered whether their activities have any Federal involvement, because critical habitat designation will not affect activities that do not have any Federal involvement; designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. In areas where the Black Warrior waterdog is present, if the species is listed, then Federal agencies would already be required to consult with the Service under section 7 of the Act on activities they fund, permit, or implement that may affect the species. If we finalize this proposed critical habitat designation, consultations to avoid the destruction or adverse modification of critical habitat would merely be incorporated into that consultation process. Therefore, for occupied and unoccupied habitat disproportionate impacts to any geographic area or sector are not likely as a result of this critical habitat designation.

In our IEM, we attempted to clarify the distinction between the effects that will result from the species being listed and those attributable to the critical habitat designation (*i.e.,* difference between the jeopardy and adverse modification standards) for the Black

Warrior waterdog's critical habitat. Because the designation of critical habitat for the Black Warrior waterdog was proposed concurrently with the listing, it has been our experience that it is more difficult to discern which conservation efforts are attributable to the species being listed and those which will result solely from the designation of critical habitat. However, the following specific circumstances in this case help to inform our evaluation: (1) The essential physical and biological features identified for critical habitat are the same features essential for the life requisites of the species; and (2) any actions that would result in sufficient harm or harassment to constitute jeopardy to the Black Warrior waterdog would also likely adversely affect the essential physical and biological features of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation in turn has been used as the basis to evaluate the probable incremental economic impacts of this proposed designation of critical habitat.

The proposed critical habitat designation for the Black Warrior waterdog is likely to result, annually, in less than two formal consultations, 23 informal consultations, and 206 technical assistance efforts related to silviculture, mining, impoundments, commercial and residential development, pipelines, agriculture and other activities that impact water quality. According to the finding in the draft screening analysis, the administrative cost of addressing adverse modification in the consultations will cost between about $410 to $9,000 per consultation. The incremental administrative cost is not likely to exceed $150,000 annually. This designation of critical habitat is not likely to cause more requirements under State or local regulations, nor is the designation expected to have perceptional effects on the markets.

Exclusions

Exclusions Based on Economic Impacts

Under section 4(b)(2) of the Act, we consider the economic impacts of specifying any particular area as critical habitat. As discussed above, we prepared an analysis of the probable economic impacts of the proposed critical habitat designation and related factors (DEA).

As we stated earlier, we are soliciting data and comments from the public on the DEA, as well as all aspects of the proposed rule and our required determinations. We may revise the proposed rule or supporting documents to incorporate or address information we receive during the public comment period. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of this species.

Exclusions Based on National Security Impacts

Under section 4(b)(2) of the Act, we consider whether there are lands within the proposed critical habitat designation where a national security impact might exist. In preparing this proposal, we have determined that the lands within the proposed designation of critical habitat for Black Warrior waterdog are not owned or managed by the Department of Defense or Department of Homeland Security, and, therefore, we anticipate no impact on national security. Consequently, the Secretary does not intend to exercise her discretion to exclude any areas from the final designation based on impacts on national security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. We consider a number of factors, including whether the landowners have developed any habitat conservation plans (HCPs) or other management plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at any tribal issues, and consider the government-to-government relationship of the United States with tribal entities. We also consider any social impacts that might occur because of the designation.

In preparing this proposal, we have determined that there are currently no HCPs or other management plans for the Black Warrior waterdog, and the proposed designation does not include any tribal lands or trust resources. We anticipate no impact on tribal lands, partnerships, or HCPs from this proposed critical habitat designation. Accordingly, the Secretary does not intend to exercise her discretion to exclude any areas from the final designation based on other relevant impacts.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our critical habitat designation is based on scientifically sound data and analyses. We have invited these peer reviewers to comment during this public comment period.

We will consider all comments and information we receive during the comment period on this proposed rule during our preparation of a final determination. Accordingly, the final decision may differ from this proposal.

Public Hearings

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register** (see **DATES**, above). Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have

developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

The Service's current understanding of the requirements under the RFA, as amended, and following recent court decisions, is that Federal agencies are only required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself, and, therefore, not required to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies will be directly regulated by this designation. Moreover, Federal agencies are not small entities. Therefore, because no small entities are directly regulated by this rulemaking, the Service certifies that, if adopted, the proposed critical habitat designation will not have a significant economic impact on a substantial number of small entities.

For the above reasons and based on currently available information, we certify that, if adopted, the proposed critical habitat designation would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. We do not expect this proposed designation of critical habitat to significantly affect energy supplies, distribution, or use. Oil and gas pipelines crossing the proposed critical habitat can be buried under the river channel (directional bored) and the contours of the channel bed returned to their natural state. Also, there are existing impoundments for power generation within the Basin but outside the proposed critical habitat. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, and critical habitat would not shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule would significantly or uniquely affect small governments because the lands adjacent to the river and streams being proposed for critical habitat are primarily owned by private landowners, which do not fit the description of ''small governmental jurisdiction.'' Therefore, a Small Government Agency Plan is not required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment as warranted.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the Black Warrior waterdog in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, nor does it establish any closures or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed and concludes that this proposed designation of critical habitat for the Black Warrior waterdog would not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this proposed critical habitat designation with, appropriate State resource agencies in Alabama. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, this proposed rule would not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical and biological features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist these local governments in long-range planning (because these local governments no longer have to wait for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) of the Act would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, the proposed rule identifies the elements of physical or biological features essential to the conservation of the species. The proposed areas of critical habitat are presented on maps, and the proposed rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This proposed rule does not contain any new collections of information that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

As discussed above, we have determined that there are no tribal lands that meet the criteria under the Act for inclusion in critical habitat.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain

language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES.** To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* and upon request from the Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rulemaking are the staff members of the Alabama Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.95, amend paragraph (d) by adding an entry for ''Black Warrior Waterdog (*Necturus alabamensis*)'' immediately following the entry for ''Houston Toad (*Bufo houstonensis*)'' to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(d) *Amphibians.*

* * * * *

Black Warrior Waterdog (*Necturus alabamensis*)

(1) Critical habitat units are depicted for Blount, Cullman, Etowah, Fayette, Jefferson, Lawrence, Marshall, Tuscaloosa, Walker, and Winston Counties, Alabama, on the maps in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of the Black Warrior waterdog consists of a riverine system with habitat to support all life-history stages of the Black Warrior waterdog, which consists of the following components:

(i) Geomorphically stable, medium to large streams (typically 4 meters (m) (13 feet (ft)) wide or greater) with:

(A) Substrate consisting of clay or bedrock with little sand, and containing abundant rock crevices, rock slabs, and leaf packs;

(B) Moderate water velocity; and

(C) Prey base of aquatic macroinvertebrates.

(ii) Water that lacks harmful levels of pollutants, including inorganic contaminants such as copper, arsenic, mercury, and cadmium; organic contaminates such as human and animal waste products; endocrine-disrupting chemicals; pesticides; nitrogen, potassium, and phosphorus fertilizers; and petroleum distillates.

(iii) Appropriate water quality parameters to support Black Warrior waterdog and primary prey base, including:

(A) Water temperature not exceeding 85 °F;

(B) Dissolved oxygen 5.5 milligrams per liter (mg/L) or greater;

(C) Turbidity of an average monthly reading of 15 nephelometric turbidity units (NTUs) above background readings;

(D) 115 mg/L of total suspended solids or less; and

(E) A specific conductance of no greater than 225 microsiemens (μS) per centimeter at 80 °F.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule.

(4) *Critical habitat map units.* Data layers defining map units were created from the USGS National Hydrography Datasets High Resolution Flowline layer using Universal Transverse Mercator (UTM) Zone 16N coordinates. Segments were mapped using 1983 UTM Zone 16 projection. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's Internet site at *http://www.fws.gov/daphne/,* at *http://www.regulations.gov* under Docket No. FWS–R4–ES–2016–0031, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) *Note:* Index map follows:

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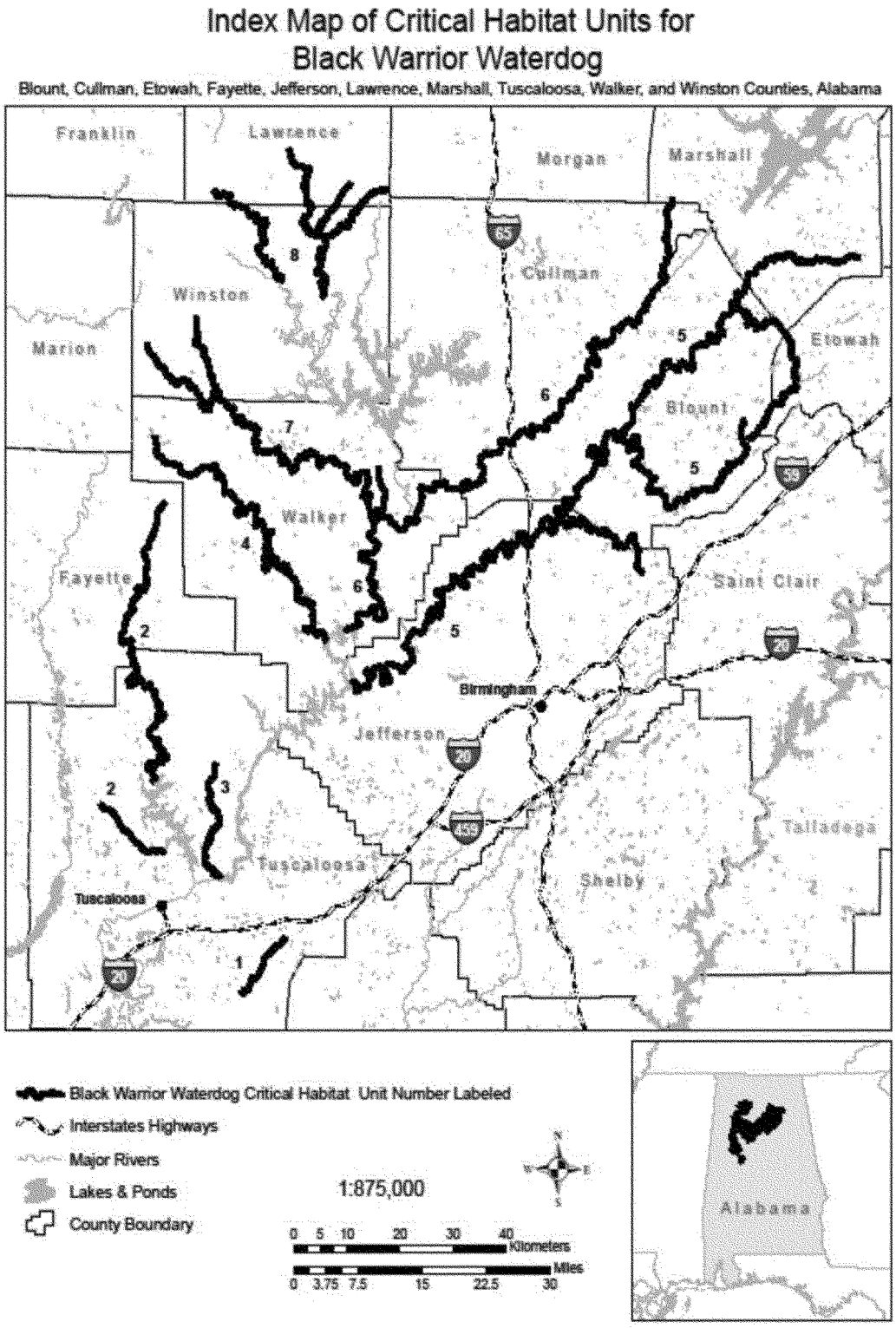
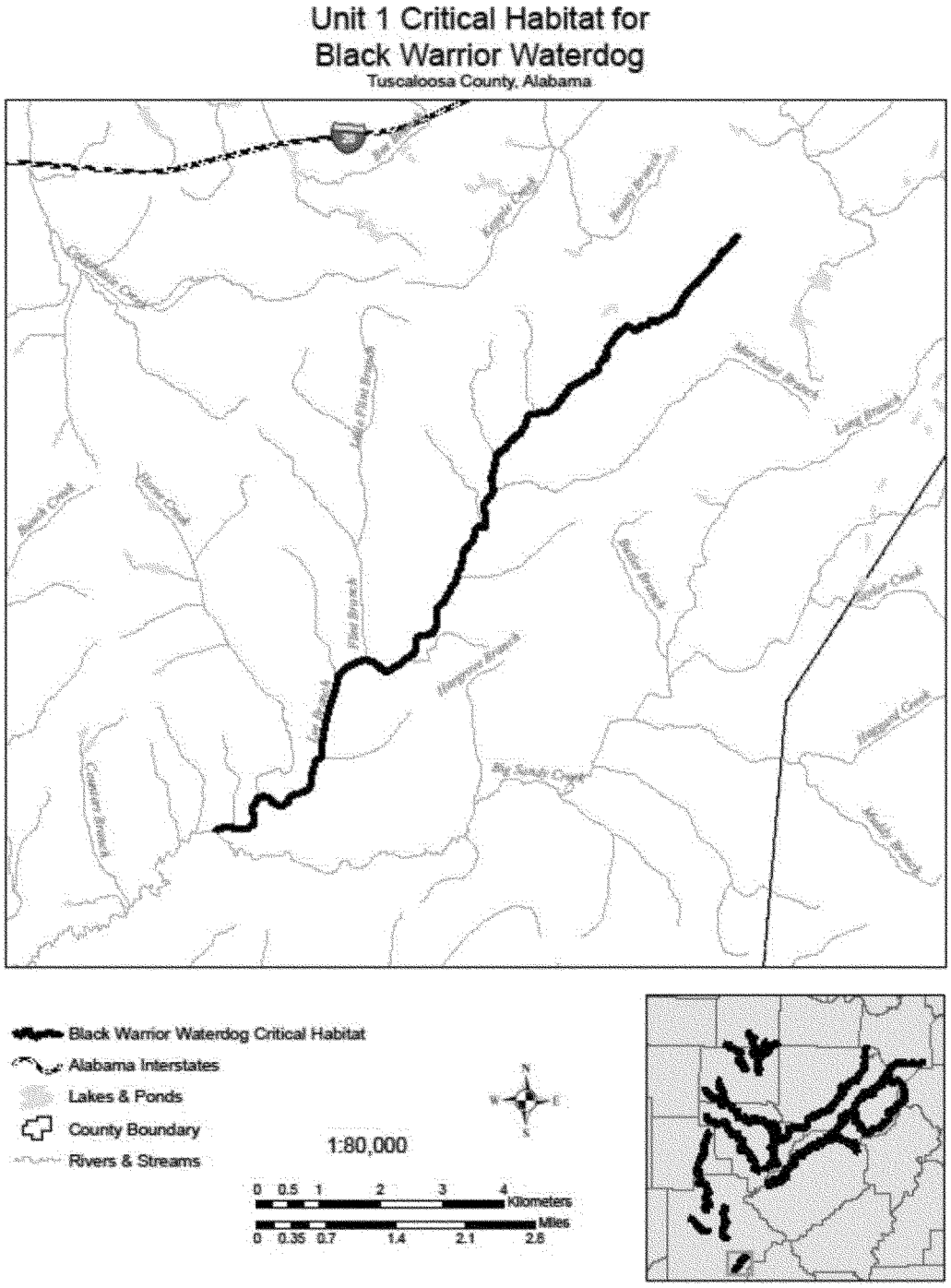


(6) Unit 1: Lye Branch.

(i) *General description:* Unit 1 consists of approximately 16 river kilometers (rkm) (10 river miles (rmi)) of stream and river habitat from the headwaters of Lye Branch to the confluence of Big Sandy Creek.

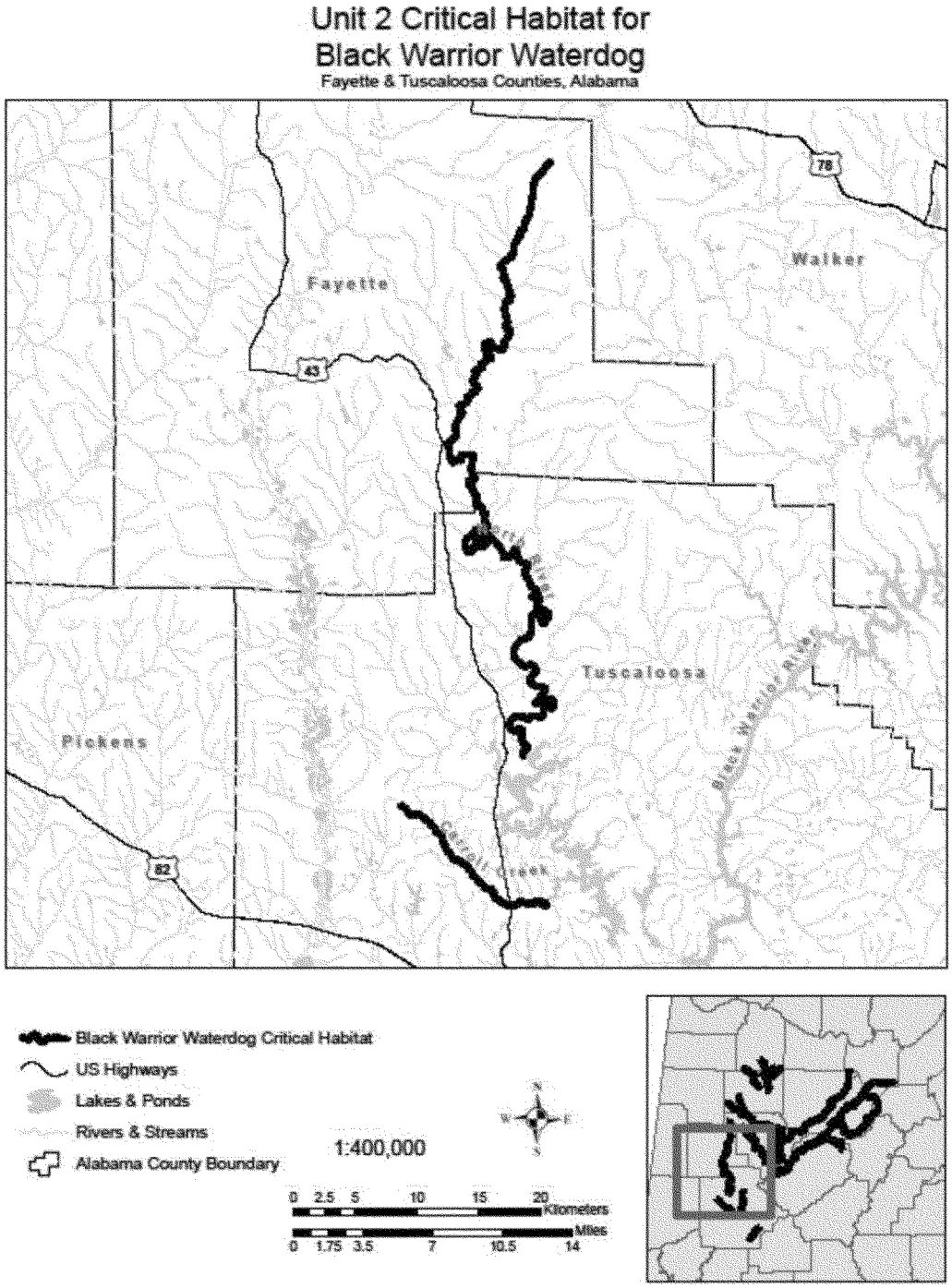
(ii) Map of Unit 1 follows:



(7) Unit 2: Lake Tuscaloosa.

(i) *General description:* Unit 2 consists of approximately 108 rkm (67 rmi) of stream and river habitat from the headwaters of North River to Tuscaloosa Lake, and from the headwaters of Carroll Creek to Tuscaloosa Lake.

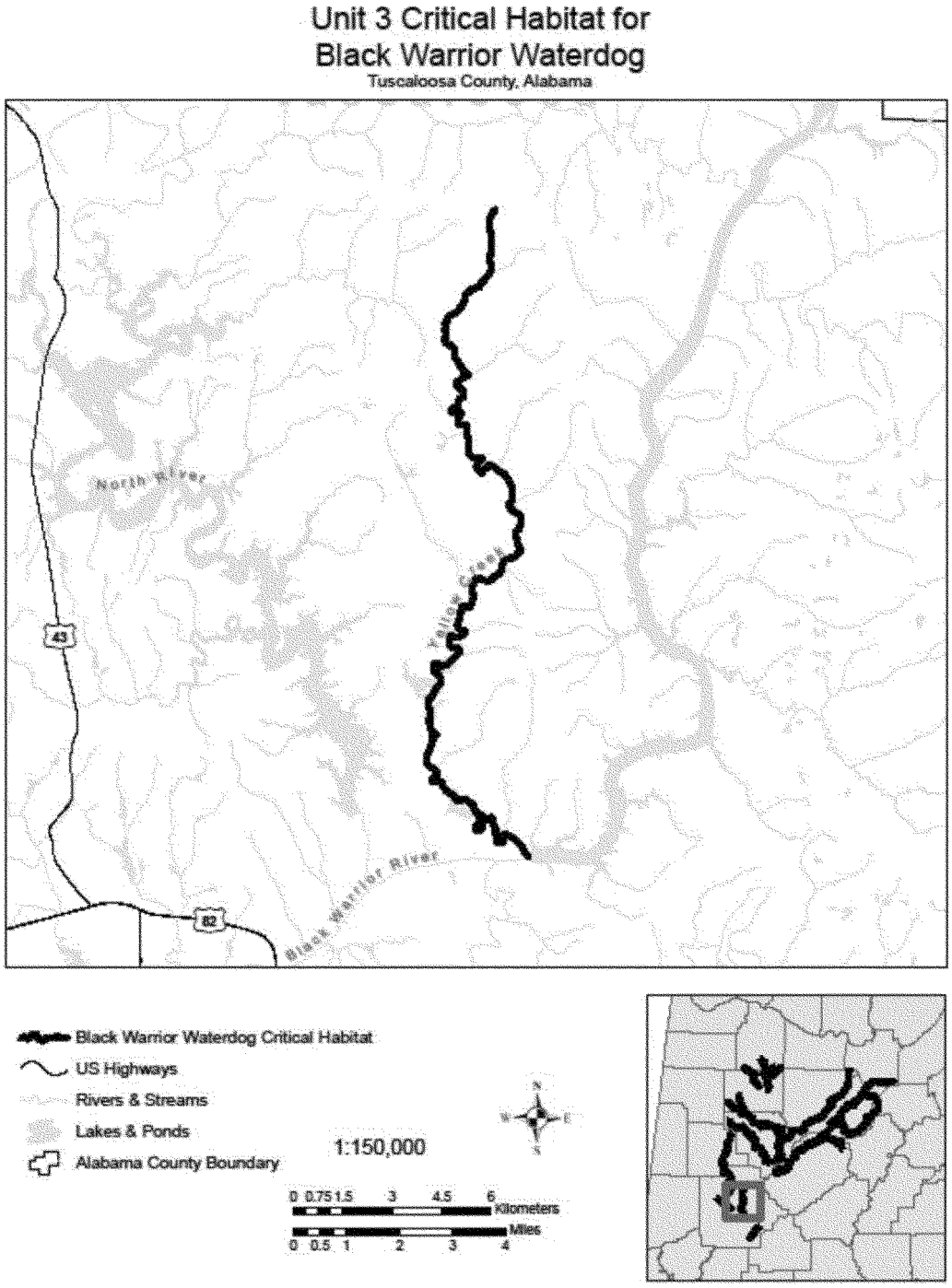
(ii) Map of Unit 2 follows:



(8) Unit 3: Yellow Creek.

(i) *General description:* Unit 3 is approximately 30 rkm (19 rmi) of stream and river habitat from the headwaters of Yellow Creek to Holt Lake.

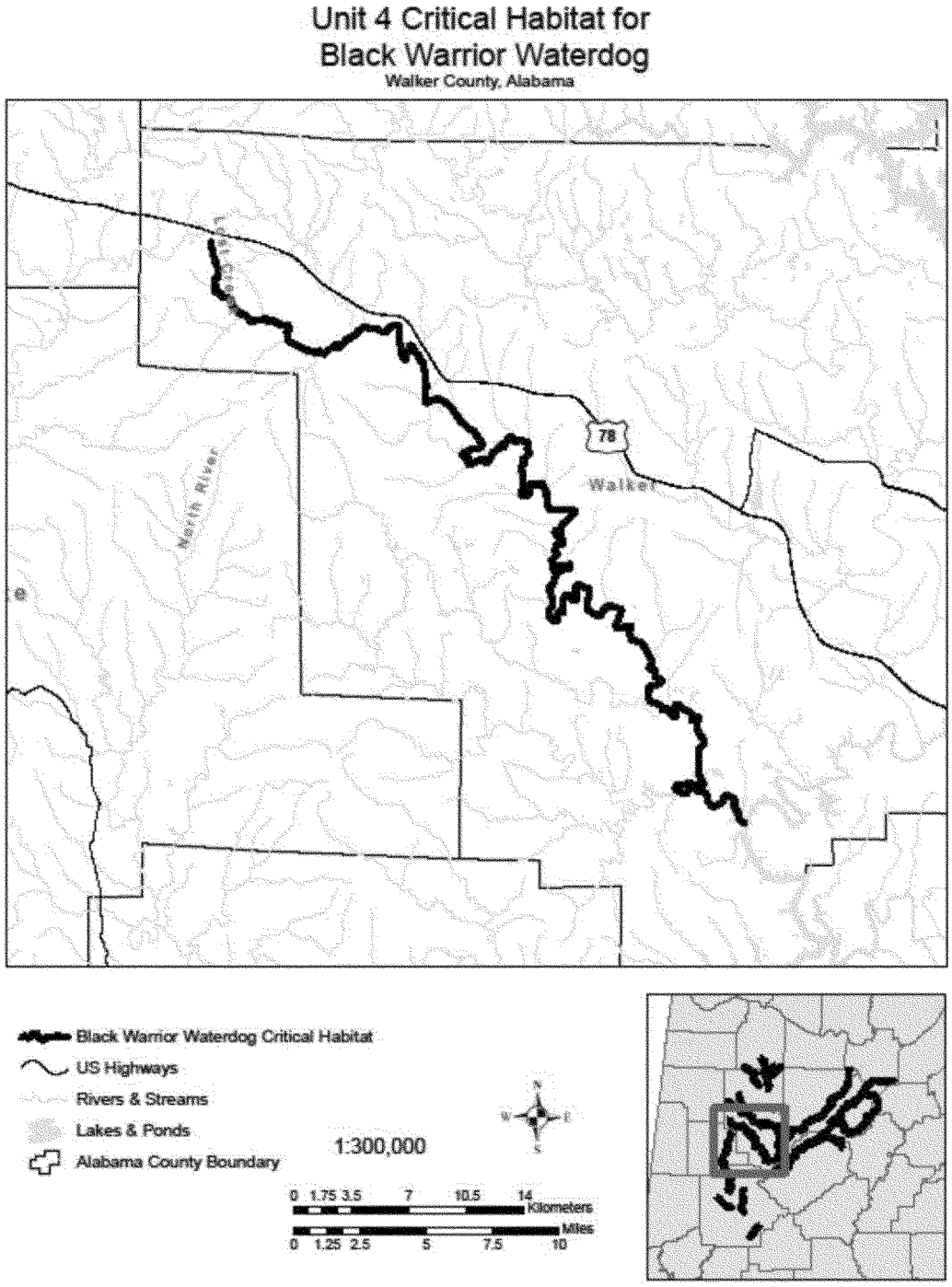
(ii) Map of Unit 3 follows:



(9) Unit 4: Lost Creek.

(i) *General description:* Unit 4 is approximately 93 rkm (58 rmi) of stream and river habitat from the headwaters of Lost Creek to Bankhead Lake.

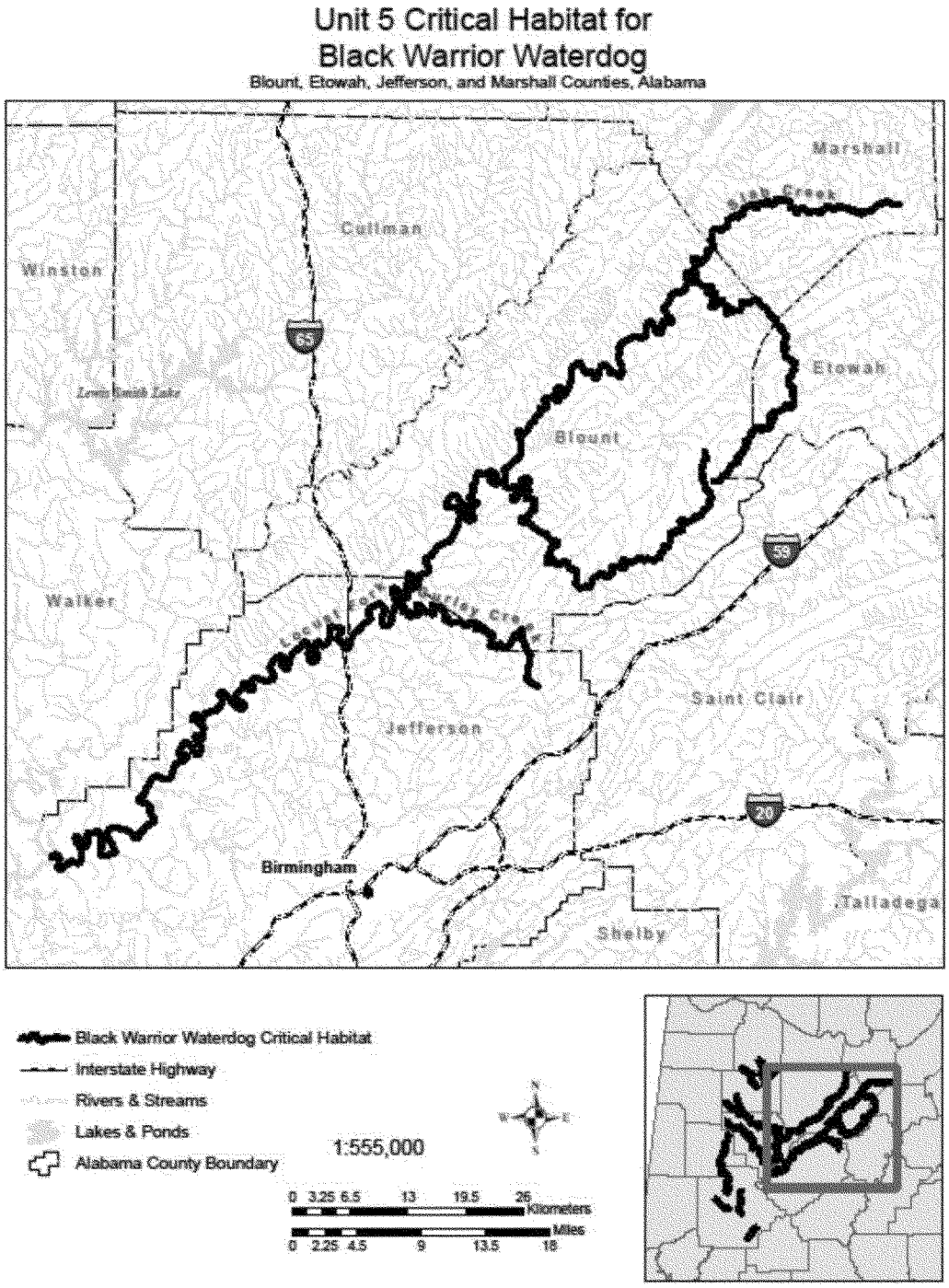
(ii) Map of Unit 4 follows:



(10) Unit 5: Locust Fork.

(i) *General description:* Unit 5 is approximately 391 rkm (243 rmi) of stream and river habitat from the headwaters of Locust Fork to Bankhead Lake, from the headwaters of Slab Creek to the confluence of Locust Fork, from the headwaters of Blackburn Fork to the confluence of Locust Fork, and from the headwaters of Gurley Creek to the confluence of Locust Fork.

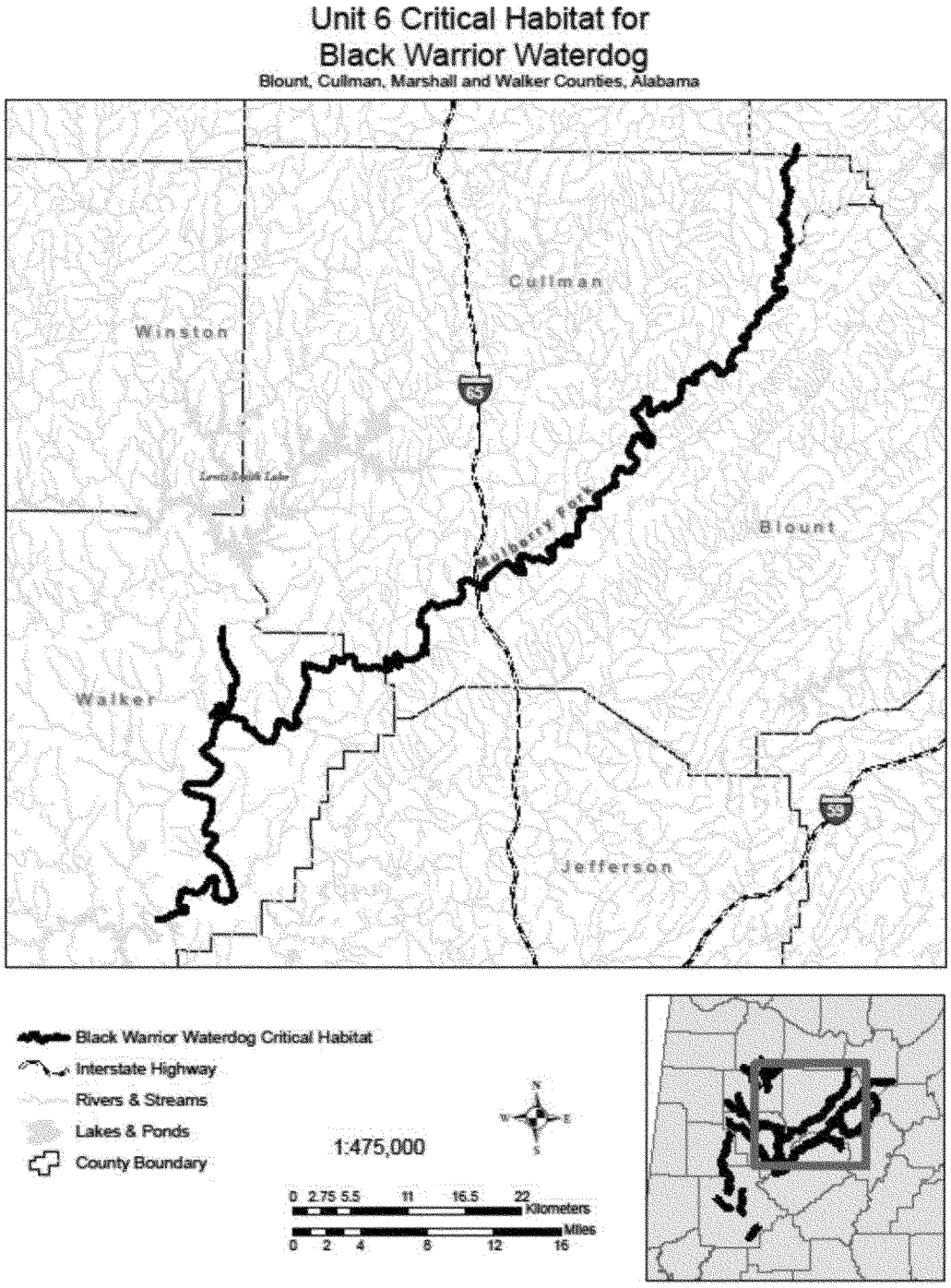
(ii) Map of Unit 5 follows:



(11) Unit 6: Mulberry Fork.

(i) *General description:* Unit 6 consists of approximately 183 rkm (114 rmi) of stream and river habitat from the headwaters of Mulberry Fork to Bankhead Lake, and from Little Blackwater Creek to the confluence of Blackwater Creek.

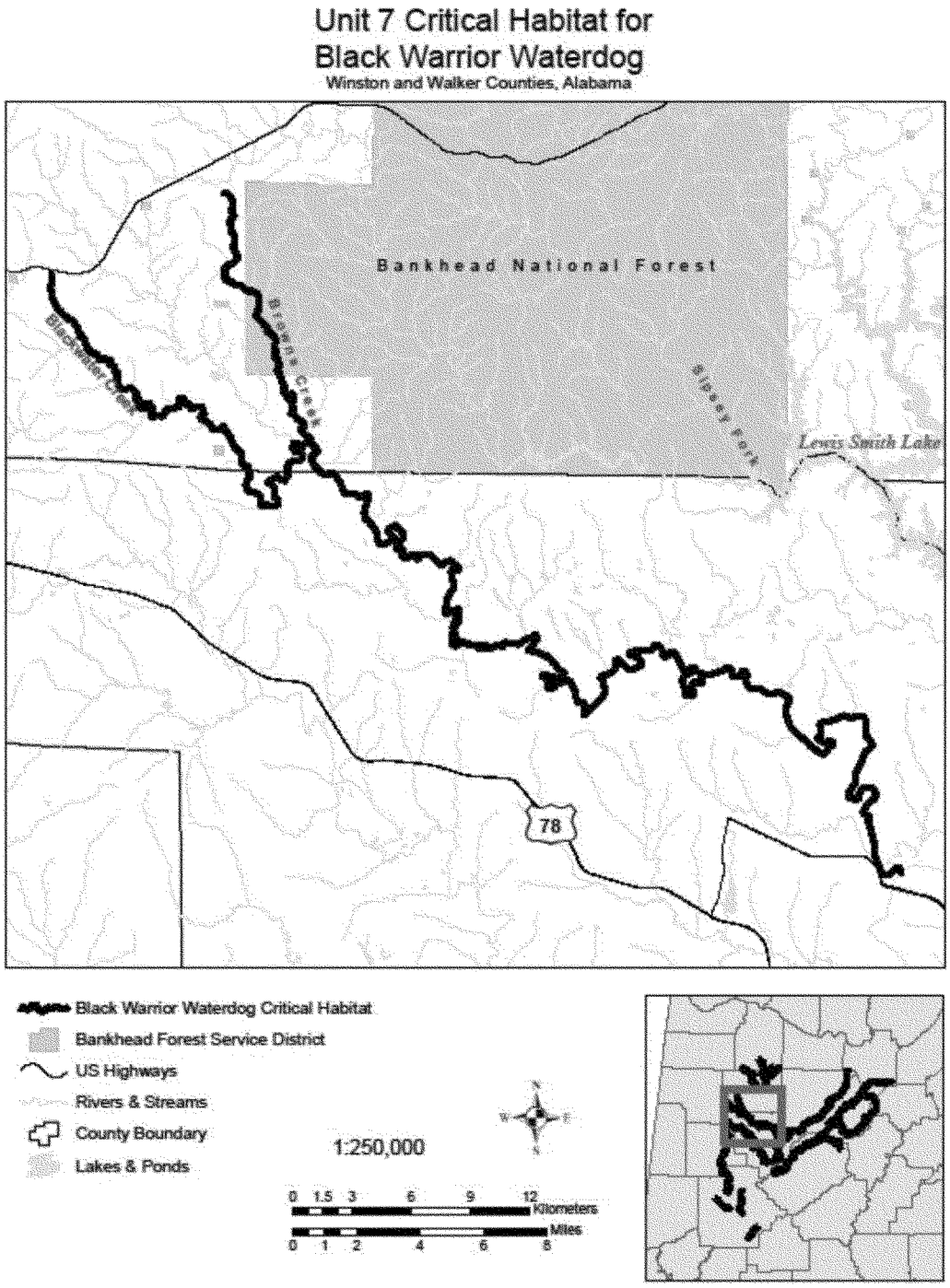
(ii) Map of Unit 6 follows:



(12) Unit 7: Blackwater Creek/Browns Creek.

(i) *General description:* Unit 7 consists of approximately 128 rkm (80 rmi) of stream and river habitat from the headwaters of Blackwater Creek to the confluence of Mulberry Fork, from the headwaters of Brown Creek to the confluence of Blackwater Creek.

(ii) Map of Unit 7 follows:

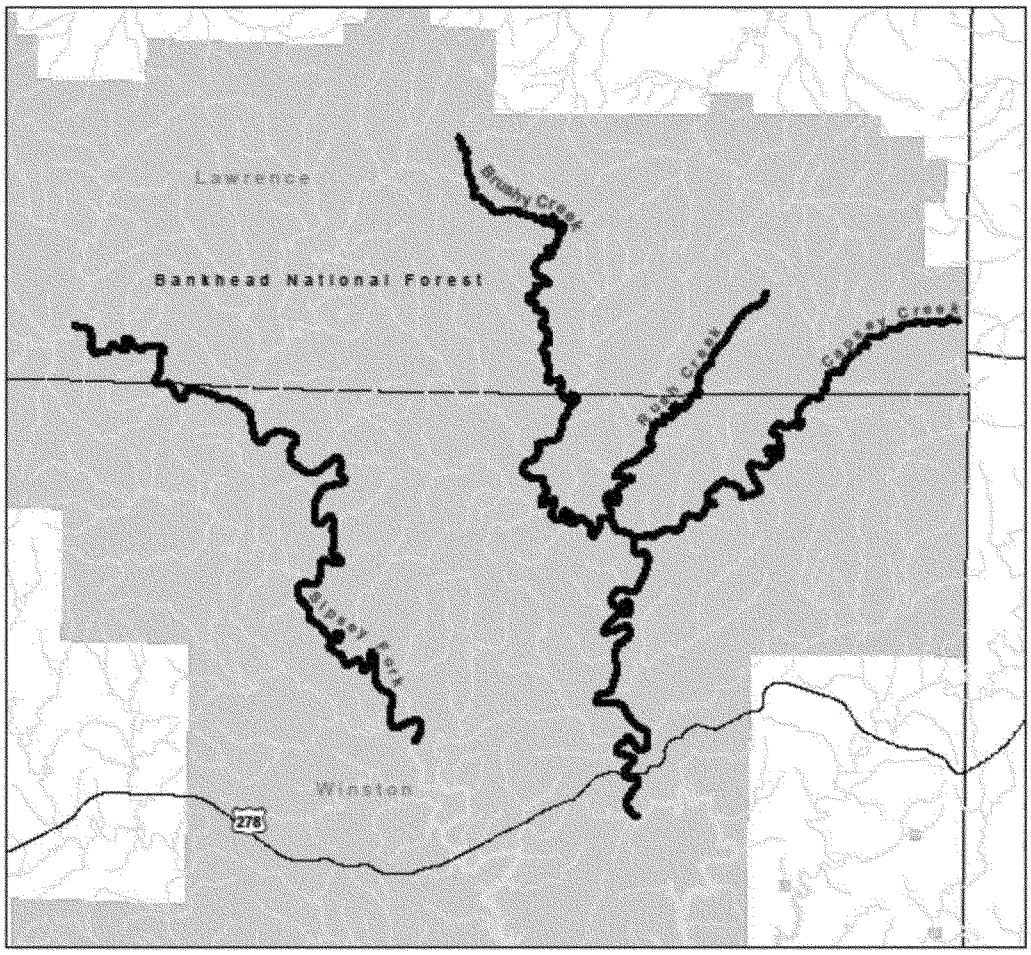


(13) Unit 8: Sipsey Fork.

(i) *General description:* Unit 8 consists of approximately 124 rkm (78 rmi) of stream and river habitat from the headwaters of Sipsey Fork to Lewis Smith Lake, from the headwaters of Brushy Creek to Lewis Smith Lake, from the headwaters of Rush Creek to the confluence of Brushy Creek, and from the headwaters of Capsey Creek to the confluence of Brushy Creek.

(ii) Map of Unit 8 follows:

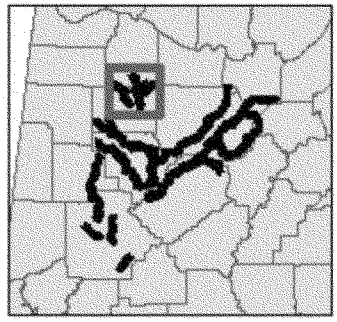
Unit 8 Critical Habitat for
Black Warrior Waterdog
Lawrence & Winstonr Counties, Alabama



Black Warrior Waterdog Critical Habitat
Bankhead Forest Service District
US Highways
Rivers & Streams
County Boundary
Lakes & Ponds

1:200,000

0 1.25 2.5 5 7.5 10 Kilometers
0 0.75 1.5 3 4.5 6 Miles



* * * * *

Dated: September 26, 2016.

Karen Hyun,

Acting Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–24118 Filed 10–5–16; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2016–0029; 4500030113]

RIN 1018–BA78

Endangered and Threatened Wildlife and Plants; Endangered Species Status for Black Warrior Waterdog

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Black Warrior waterdog (*Necturus alabamensis*), an aquatic salamander from the Black Warrior River Basin of Alabama, as an endangered species under the Endangered Species Act (Act) because of the severity and immediacy of threats currently impacting the species. If we finalize this rule as proposed, it would extend the Act's protections to this species.

DATES: We will accept comments received or postmarked on or before December 5, 2016. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by November 21, 2016.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R4–ES–2016–0029, which is the docket number for this rulemaking. Then click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R4–ES–2016–0029, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see *Public Comments,* below, for more information).

FOR FURTHER INFORMATION CONTACT: William Pearson, Field Supervisor, U.S. Fish and Wildlife Service, Alabama Ecological Services Field Office, 1208 Main Street, Daphne, AL 36526; by telephone 251–441–5184; or by facsimile 251–441–6222. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Information Requested

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The Black Warrior waterdog's biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act (16 U.S.C. 1531 *et seq.*) directs that determinations as to whether any species is a threatened or endangered species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Public Hearing

Section 4(b)(5) of the Act requires us to hold one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register** (see **DATES**, above). Such requests must be sent to the address shown in the **FOR FURTHER INFORMATION CONTACT** section. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our listing determination is based on scientifically sound data, assumptions, and analyses. The peer reviewers will inform our determination. We invite comments from the peer reviewers during this public comment period.

Previous Federal Actions

The Black Warrior waterdog (then known as the Sipsey Fork waterdog) was first identified as a Category 2 species in our 1982 Review of Vertebrate Wildlife for Listing as Endangered or Threatened Species (47 FR 58454, December 30, 1982). Category 2 candidates were defined as taxa for which we had information that proposed listing was possibly appropriate, but for which substantial data on biological vulnerability and threats were not available to support a proposed rule at the time. The species remained on subsequent annual candidate notices of review (CNORs) (56 FR 58804, November 21, 1991; 59 FR 58982, November 15, 1994). In the February 28, 1996, CNOR (61 FR 7596), we discontinued the designation of Category 2 species as candidates; therefore, the Black Warrior waterdog was no longer a candidate species.

In 1999, the Black Warrior waterdog was again added to the candidate list (64 FR 57534, October 25, 1999). At present, candidates are those fish, wildlife, and plants for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing rule is precluded by other higher priority listing activities. The Black Warrior waterdog was included in all of our subsequent annual CNORs (66 FR 54808, October 30, 2001; 67 FR 40657, June 13, 2002; 69 FR 24876, May 4, 2004; 70 FR 24870, May 11, 2005; 71 FR 53756, September 12, 2006; 72 FR 69034, December 6, 2007; 73 FR 75176, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; 80 FR 80584, December 24, 2015). On May 11, 2004, we were petitioned to list the Black Warrior waterdog. The petitioner provided information the Service already had in its files and had used to identify the species as warranted for listing. As a result, no further action was taken on the petition. The Black Warrior waterdog has a listing priority number of 2, which means that the candidate is a species with threats that are both imminent and high in magnitude.

Species Information

Taxonomy and Species Description

The Black Warrior waterdog is a large, aquatic, nocturnal salamander that permanently retains a larval form and external gills throughout its life (Conant and Collins 1998, pp. 419–420). Its head and body are depressed; its tail is compressed laterally, and each of its four legs has a foot with four toes. Larval Black Warrior waterdogs (28 to 48 millimeters (mm) (1 to 2 inches (in) total length)) are dark brown or black on their dorsum (upper surfaces) and have two light stripes running along their sides (Bailey 2000, p. 1). Adults may reach a maximum of 240 mm (9.5 in) total length; subadults (40 to 100 mm (1.5 to 4 in) total length) do not have the stripes that are present on larvae and are not conspicuously marked, although they do have a dark stripe extending from the nostril through the eye to the gills. Adults are usually brown, may be spotted or unspotted, and retain the dark eye stripe (Bailey 2000, p. 1). The ventral surface of all age classes is plain white.

In 1937, Viosca (1937, pp. 120–138) described the Black Warrior waterdog as *Necturus alabamensis*. In subsequent years, the name *N. alabamensis* was mistakenly applied to other waterdogs within the peer-reviewed literature. The taxonomy of the Black Warrior waterdog was clarified by Bart *et al.* (1997, pp. 192–201), and the original description by Viosca (1937, pp. 120–138) remains valid. The available taxonomic information on *N. alabamensis* has been carefully reviewed, and we conclude that this species is a valid taxon.

Distribution

The Black Warrior waterdog (waterdog) is found only within streams within the Black Warrior River Basin (Basin) in Alabama. The waterdog inhabits streams above the Piedmont Fall Line (the contact between the Coastal Plain and the adjacent Upland provinces) within the Basin in Alabama, including parts of the North River, Locust Fork, Mulberry Fork, and Sipsey Fork drainages and their tributaries.

Waterdog habitat is similar to that of the flattened musk turtle (*Sternotherus depressus*), a species listed as threatened under the Act (52 FR 22418; June 11, 1987) and which is restricted to permanent streams above the Fall Line in the Black Warrior Basin (Mount 1975, p. 303). The waterdog received little attention between the time it was described in 1937 and the mid-1980s, when it was found during surveys in the Tennessee-Tombigbee Waterway (Ashton and Peavy 1985, pp. 1–15). During this time, reference to the species, beyond field guides and summary descriptions, could be found in only three scientific publications and one unpublished doctoral dissertation (Hecht 1958, pp. 4, 17; Neil 1963, pp. 166–174; Gunter and Brode 1964, pp. 114–126; Brode 1969, pp. 21–22, 62–64, 132).

There are a total of 11 historical records from sites in Blount, Tuscaloosa, Walker, and Winston Counties, Alabama. The historical waterdog records are sites from 10 streams or major segments: Sipsey Fork (two sites) of the Black Warrior River and Brushy Creek (a tributary to Sipsey Fork) in Winston County; Locust Fork and Blackburn Fork of the Little Warrior River in Blount County; Mulberry Fork, Lost Creek, and Blackwater Creek in Walker County; and Yellow Creek, North River, and Black Warrior River in Tuscaloosa County (Viosca 1937, pp. 120–122, 137–138; Ashton and Peavy 1985, pp. 1–15; Bailey 1992, pp. 7–9, 16–27; Bailey 1995, pp. 16–27; Bart *et al.* 1997, pp. 194–195, 198–200; Guyer 1997, p. 9; Bailey 2000, pp. 3–5). Only two of these records (Black Warrior River ''near Tuscaloosa'' in 1914 and 1937, and Mulberry Fork ''at Cordova'' in 1938) were documented prior to the mid-1980s. These localities have since been inundated by impoundments.

Bailey (2000, pp. 1–24) conducted a habitat assessment of the 11 sites verified as Black Warrior waterdog localities prior to 1993. Bailey assessed the sites using subjective impressions of habitat suitability using parameters such as stream width and depth, water quality, substrate, structure (crevices, logs, etc.), and invertebrate fauna. Sites were stratified into four categories: Good to excellent, moderate, poor to unsuitable, and impounded. Bailey concluded that one (9 percent) of the sites was good to excellent, four (36 percent) were of moderate quality, two (18 percent) were poor to unsuitable, and four (36 percent) were in impoundments.

Current Range and Distribution

At least 112 sites have been sampled for the Black Warrior waterdogs since 1990 (1990, 1991, 1992, 1994, 1996, 1997, 1998, 2008, 2009, 2011, 2012, and

2013) (Bailey 1995, pp. 16–27; Guyer 1997, pp. 19–21 and 1998, pp. 6–7; Durflinger-Moreno *et al.* 2006, pp. 73–74; Stoops *et al.* 2010, p. 6; Alabama Natural Heritage Program 2011, p. 4; 78 FR 70104, November 22, 2013, p. 70125; Godwin 2014, pers. comm.; Godwin 2013b, p. 1). Survey sites included all stream localities within the range of the species that approached or intersected roads and had appropriate habitat. Since 1990, the species has been reported from only 14 sites. These sites are in Blount (Blackburn Fork of the Little Warrior River), Marshall (Slab Creek, tributary to Locust Fork), Tuscaloosa (Yellow Creek, North River, Carroll Creek, Lye Branch, Mulberry Fork), Walker (Lost Creek, Little Blackwater Creek), and Winston (Sipsey Fork, Blackwater Creek, Browns Creek, Brushy Creek, Capsey Creek) Counties, Alabama. Guyer (1997, pp. 3–4) did a statistical analysis of all waterdog field survey data. The relationship between cumulative number of site visits and the cumulative number of sites containing waterdogs indicated that 200 additional surveys would be needed to discover a single new locality for the species (Guyer 1997, p. 4).

No waterdogs were recently captured at any historic localities outside of William Bankhead National Forest (BNF). Therefore, we believe the populations are in decline outside of BNF. Only through the use of environmental DNA (eDNA) have we been able to determine that the species is still present at some historic locations. Environmental DNA is a surveillance tool used to monitor for the genetic presence of an aquatic species. According to Strickler (2015, p. 1),''Environmental DNA has proven to be a sensitive, accurate, and cost-efficient tool for species detection in aquatic environments and is especially attractive because it's non-invasive and poses no risk to aquatic animals. Even when an aquatic animal can't be seen or heard, it leaves traces of itself in the water by shedding skin, excreting waste, releasing gametes and decomposing. Investigators collect a water sample to detect the target species' DNA and determine whether the species has recently been in the water body.'' Field surveys conducted between 2008 and 2012 at historical localities indicated only one population was still persisting in the BNF, Winston County (Stoops *et al.* 2010, p. 1–6; Godwin 2014, pers. comm.; Godwin 2013a, p. 1 and 2013b, p. 1). Additionally, the use of eDNA in 2013 and 2014 indicated that Black Warrior waterdogs were still present in Locust Fork, Gurley Creek, Rush Creek (BNF property), and Yellow Creek (Godwin 2014, pers. comm.), although no waterdogs were captured at the time.

Population Estimates and Status

Each of the 14 sites verified as a Black Warrior waterdog locality (see above) represented individual populations. Very little is known about the status of these populations. Only one or two animals were captured at survey sites with the exception of Sipsey Fork, which was chosen for an indepth study because waterdogs were most common there (Durflinger-Moreno *et al.* 2006, pp. 70–71). Fifty-two waterdogs were captured at the Sipsey Fork site over a 3-year period representing 173,160 trap hours (1 waterdog/3,330 trap hours). Thirty-five (67 percent) animals were adults, 5 (10 percent) were subadults, and 12 (23 percent) were larvae. The number of adult males and females captured was not significantly different from an expected 1:1 sex ratio (Durflinger-Moreno *et al.* 2006, p. 79). In the Sipsey Fork, the high number of sexually mature individuals indicates that recruitment and survival rates of the young age classes may be low (Durflinger-Moreno *et al.* 2006, p. 79).

The viability of any Black Warrior waterdog population, including Sipsey Fork population, is unknown.

Habitat

Rocks, submerged ledges, and other cover play important roles in determining habitat suitability for the Black Warrior waterdog (Ashton and Peavy 1986, p. 64). Semi-permanent leaf beds (where they exist) are visited frequently (Ashton and Peavy 1986, p. 64). Larvae and adult waterdogs are reliably found only in these submerged leaf beds, and they may use them for both shelter and foraging habitat (Bailey 2000, p. 3). Guyer (1997, pp. 1–21) analyzed habitats to distinguish sites with waterdogs from those lacking the species. He found that Black Warrior waterdogs were associated with clay substrates lacking silt, wide and shallow stream morphology, increased snail and dusky salamander (*Desmognathus* spp.) abundance, and decreased Asiatic clam (*Corbicula fluminea*) occurrence. Durflinger-Moreno *et al.* (2006, pp. 70–80) completed an additional assessment of 112 localities surveyed for waterdogs. At a regional scale, Black Warrior waterdogs were associated with stream depths of 1 to 4 meters (m) (3.3 to 13.1 feet (ft)), reduced sedimentation, and large leaf packs (leaves that fall into streams accumulate in packs usually behind branches, rocks, and other obstructions) supporting mayfly (*Ephemeroptera* spp.) and caddisfly (*Trichoptera* spp.) larvae.

Biology

Very little is known about the life history of the Black Warrior waterdog. Additionally, data are generally limited for other species of the southeastern *Necturus* waterdogs, as well.

Reproduction in the Black Warrior waterdog is aquatic. Egg disposition sites and clutch sizes are unknown. However, in the closely related Gulf Coast waterdog (*Necturus beyeri*), females attach their eggs singly to the undersides of underwater substrate (summarized in Guyer 2005, p. 868). Sexually active Black Warrior waterdog adults have been found in rock crevices (Bailey 2005, p. 867), and thus egg deposition may occur at these sites. Clutch sizes ranging from 4 to 40 eggs were reported in a summary of research conducted on the Gulf Coast waterdog (Guyer 2005, p. 868). Ashton and Peavy (1986, p. 64) collected post hatchling Black Warrior waterdog larvae in December; this suggests that nesting may occur in late spring or summer. Reproductive maturity is probably attained in the third winter or at 2.5 years of age (Bailey 2005, p. 867).

Aestivation (spending the summer in a state of inactivity) in Black Warrior waterdogs is suspected, as no specimens have been collected during the summer (Bailey 2005, p. 867). A similar seasonal pattern of activity primarily in winter and spring is also seen in other species of *Necturus* (Dundee 2005, p. 872; Guyer 2005, p. 868).

Larval and adult Black Warrior waterdogs are assumed to be opportunistic carnivores, but prey taken in the wild has not been described. Adults are attracted to traps baited with fish-flavored cat food (Bailey 2005, p. 867). Captive Black Warrior waterdogs have eaten small fish and earthworms (Bailey 2005, p. 867). Crayfish, isopods, amphipods, freshwater clams, and insects (including mayflies, caddisflies, dragonfly naiads, dytiscid beetles, and midges) have been reported as prey items in Gulf Coast waterdogs (Guyer 2005, p. 868).

Home ranges of Black Warrior waterdogs are likely small as in other species of the southeastern *Necturus.* As much more is known about the Gulf Coast waterdog, we are basing our analysis on its mark-recapture study where all recaptures were within 64 m (210 ft) of the original capture and release site (summarized in Guyer 2005, p. 868).

Summary of Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination. Each of these factors is discussed below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Water quality degradation is the primary threat to the continued existence of the Black Warrior waterdog. Bailey (2000, pp. 19–20) considered water quality degradation to be the primary reason for the extirpation of this species over much of its historical range in the upper Black Warrior River system. Changes in water chemistry and flow patterns, resulting in a decrease in water quality and quantity have detrimental effects on salamander ecology because they can render aquatic habitat unsuitable for salamanders. Substrate modification is also a major concern for aquatic salamander species (Geismar 2005, p. 2; O'Donnell *et al.* 2006, p. 34). Unobstructed interstitial space (pertaining to being between things, especially between things that are normally close) is a critical component of the habitat for the Black Warrior waterdog, because it provides cover from predators and habitat for their macroinvertebrate prey items within the sites. When the interstitial spaces become compacted or filled with fine sediment, the amount of available foraging habitat and protective cover for salamanders with these behaviors is reduced, resulting in population declines (Welsh and Ollivier 1998, pp. 1, 128; Geismar 2005, p. 2; O'Donnell *et al.* 2006, p. 34). Most streams surveyed for the Black Warrior waterdog showed evidence of water quality degradation, and many appeared biologically depauperate (limited aquatic species diversity) (Bailey 1992, p. 2 and 1995, p. 11; Durflinger-Moreno *et al.* 2006, p. 78).

Discharges

Sources of point (point source discharge) and nonpoint (land surface runoff) pollution in the Basin have been numerous and widespread. Point pollution is generated from inadequately treated effluent from industrial plants, sanitary landfills, sewage treatment plants, and drain fields from individual private homes (Service 2000, pp. 12–13). Nonpoint pollution originates from agricultural activities, poultry and cattle feedlots, abandoned mine runoff, construction, silviculture, failing septic tanks, and contaminated runoff from urban areas (Deutsch *et al.* 1990, pp. 1–62, Upper Black Warrior Technical Task Force 1991, p. 1; O'Neil and Sheppard 2001, p. 2). These sources contribute pollution to the Basin via sediments, fertilizers, herbicides, pesticides, animal wastes, septic tank and gray water leakage, and oils and greases. Water quality and native aquatic fauna have declined as a result of this pollution, which causes nitrification, decreases in dissolved oxygen concentration, and increases in acidity and conductivity. These alterations have a direct effect on the survival of Black Warrior waterdogs, which, due to their highly permeable skin (Duellman and Trueb 1986, p. 197) and external gills, are very sensitive to declines in water quality and oxygen concentration.

Urbanization is a significant source of water quality degradation that can reduce the survival of aquatic organisms, such as the Black warrior waterdog (Bowles *et al.* 2006, p. 119; Chippindale and Price 2005, pp. 196–197). Urban development leads to various stressors on aquatic systems, including increased frequency and magnitude of high flows in streams, increased sedimentation, increased contamination and toxicity, and changes in stream morphology and water chemistry (Coles *et al.* 2012, pp. 1–3, 24, 38, 50–51). Urbanization can also impact aquatic species by negatively affecting their invertebrate prey base (Coles *et al.* 2012, p. 4). Urbanization also increases the sources and risks of an acute or catastrophic contamination event, such as a leak from an underground storage tank or a hazardous materials spill on a highway. Several researchers have examined the negative impact of urbanization on stream salamander habitat by making connections between salamander abundances and levels of development within the watershed. In a 1972 study on the dusky salamander (*Desmognathus fuscus*) in Georgia, Orser and Shure (p. 1,150) found a decrease in stream salamander density with increasing urban development. A similar relationship between salamander populations and urbanization was found in another study on the dusky salamander, two-lined salamander (*Eurycea bislineata*), southern two-lined salamander (*Eurycea cirrigera*), and other species in North Carolina (Price *et al.* 2006, pp. 437–439; Price *et al.* 2012a, p. 198), Maryland, and Virginia (Grant *et al.* 2009, pp. 1,372–1,375). Willson and Dorcas (2003, pp. 768–770) demonstrated the importance of examining disturbance within the entire watershed as opposed to areas just adjacent to the stream by showing that salamander abundance in the dusky and two-lined salamanders is most closely related to the amount and type of habitat within the entire watershed.

The large population centers such as Birmingham, Tuscaloosa, and Jasper contribute substantial runoff to the Basin. The watershed occupied by these three cities contains more industrial and residential land area than other river basins in Alabama. Streams draining these areas have a history of serious water quality problems, as described above. Species of fish, mussels, and snails (Mettee *et al.* 1989, pp. 14–16; Hartfield 1990, pp. 1–8), and populations of the flattened musk turtle (Service 1990, p. 3), have been extirpated from large areas of the watershed primarily due to water quality degradation. For example, Mettee *et al.* (1989, pp. 14–16) noted the absence of at least nine fish species from streams draining the Birmingham metropolitan area where they had previously been common, and Hartfield (1990, pp. 1–8) documented the extirpation of 39 to 40 species of mussels from individual tributaries of the Black Warrior River. In addition, highway construction may reroute streams or change their shape.

Forest Management

Forestry operations and road construction are also sources of nonpoint pollution when best management practices (BMPs) are not followed to protect streamside management zones (Hartfield 1990, pp. 4–6; Service 2000, p. 13). Logging can cause erosion, siltation, and streambed structural changes from the introduction of tree slash. Forestry road construction, stream crossings, and bridge replacements can also result in increased sedimentation, and runoff may introduce toxic chemicals into streams. According to Alabama's BMPs for forestry, stream management zones (SMZs) should be 35 ft (50 ft for

sensitive areas). Recently, the forest industry has begun to self-regulate SMZs through a certification program in which mills will not accept timber from foresters who do not comply with SMZs.

Surface Mining

Surface mining represents another threat to the biological integrity of streams in the Basin and has undoubtedly, in the past, affected the distribution of the Black Warrior waterdog (Bailey 1995, p. 10). Strip mining for coal results in hydrologic problems (*i.e.,* erosion, sedimentation, decline in groundwater levels, and general degradation of water quality) that affect many aquatic organisms (Service 2000, p. 12). Runoff from coal surface mining generates pollution through acidification, increased mineralization, and sediment loading. Impacts are generally associated with past activities and abandoned mines, since presently operating mines are required to employ environmental safeguards established by the Federal Surface Mining Control and Reclamation Act of 1977 (30 U.S.C. 1201 *et seq.*) and the Clean Water Act of 1972 (33 U.S.C. 1251 *et seq.*) (Service 2000, p. 12). Old, abandoned mines will continue to contribute pollutants to streams into the future.

Recently, new coal mines, which have the potential of discharging additional pollutants into the waters within the range of the Black Warrior waterdog, have been proposed in the Sipsey Fork and the Mulberry Fork (Dillard 2011, pers. comm.; Alabama Surface Mining Commission 2012, pp. 1–4).

Sedimentation

Sedimentation has probably caused similar declines for Black Warrior waterdogs as it has for the flattened musk turtle, which also occurs in the upper Basin. Sedimentation in this system has negatively affected the flattened musk turtle by: (1) Reduction of mollusks and other invertebrates used as food; (2) physical alteration of rocky habitats where animals forage and take cover, and (3) accumulation of substrate in which chemicals toxic to animals and their prey persist (Dodd *et al.* 1988, pp. 1–61). The Sipsey Fork of the Black Warrior River is the best remaining locality for the Black Warrior waterdog (Guyer 1998, p. 2). Bailey and Guyer (1998, pp. 77–83) completed a study of the flattened musk turtle at this site. They found that the turtle population was declining and suggested that habitat quality is also deteriorating. Because of similar habitat use, deteriorating habitat quality may likewise affect the Black Warrior waterdog.

Black Warrior waterdogs are vulnerable to sedimentation, and the associated pollution concentrated in sediments, as they spend virtually all of their lives at the stream bottom and would be in almost constant contact with any toxic substances that may be present (Bailey 1995, p. 10). The skin of amphibians is highly permeable, and water is exchanged readily with the environment. As a result, the respiration (breathing) and osmoregulation (balance of body fluids) of Black Warrior waterdogs would be negatively affected by toxic sediments. Excessive sediments also impact the hard stream and river bottoms by making the habitat unsuitable for feeding or reproduction of Black Warrior waterdogs. For example, sediments have been shown to affect respiration, growth, reproductive success, and survival of aquatic insects and fish (Waters 1995, pp. 173–175) that serve as food sources for the waterdog (Bailey 2005, p. 867). Potential sources of pollution and associated sedimentation within a watershed include virtually all activities that disturb the land surface, and all localities currently occupied by the Black Warrior waterdog are affected by varying degrees by sedimentation (O'Neil and Sheppard 2001, Appendix B, p. 5). Sedimentation or siltation is one of the most severe threats to the Black Warrior River (Black Warrior Riverkeeper 2012, p. 1). The Black Warrior River watershed receives significant pollutant loading from activities related to the human population and land-use activities, including sedimentation from construction, forestry, mining, agriculture, and channelization of stream segments (Black Warrior River Watershed Management Plan n.d., p. 4.3).

Impoundments

Creation of large impoundments, behind Bankhead, Lewis, and Holt dams, within the Basin has flooded thousands of square hectares (acres) of habitat previously considered appropriate for the Black Warrior waterdog. Hartfield (1990, p. 7) summarized the number of miles of streams affected by impoundments in the Basin. He found that the entire main channel of the Black Warrior River, over 272 kilometers (km) (170 miles (mi)), has been affected. Impoundments do not have the shallow, flowing water preferred by the species. As a result, they are likely marginal or unsuitable habitat for the salamander. The abundance of predatory fish in impoundments further renders these lakes unsuitable for the Black Warrior waterdog. Impoundments have been entrapments for waterdogs.

Two historical populations of the Black Warrior waterdog have been lost due to impoundments. Of the remaining historical populations, only one appears to be holding on in numbers sufficient enough to be captured regularly (Sipsey Fork on BNF). A second population is present on Locust Fork, but the numbers of waterdogs present appears low, based on the erratic capture success at the site. Through the use of eDNA, Godwin (2014, pers. comm.) identified a historical site on Yellow Creek as having Black Warrior waterdogs present. A couple years later, in 2016, a Black Warrior waterdog was indeed captured in Yellow Creek. Further, Godwin also identified two new sites in the Basin through the eDNA method, but as of yet, no waterdogs have been captured (recently) at any of the eDNA sites. Based on evolution biology, the current known and suspected populations are isolated and fragmented by human-made barriers, further compounding the effects of inbreeding and contributing to the species' decline.

Summary of Factor A

The historical loss of habitat is currently, and projected to continue to be, a threat to the Black Warrior waterdog. Habitat loss also amplifies the threat from point and nonpoint source water and habitat quality degradation, accidental spills, and violation of permitted discharges. Due to the limited extent of the habitat currently occupied by the species and the severity and magnitude of this threat, we consider that the present or threatened destruction, modification, or curtailment of habitat and range represents a threat to the Black Warrior waterdog. While changes to management and operating procedures have reduced impacts to the river system, ongoing activities continue to impact water quality.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Based on best available data, there is no evidence that overutilization for commercial, recreational, scientific, or educational purposes is a threat to the Black Warrior waterdog.

Factor C. Disease or Predation

No diseases or incidences of predation have been reported for the Black Warrior waterdog. Also, Bart and Holzenthal (1985, p. 406) found that there is no natural evidence of predation

on *Necturus* spp. by fish in creeks and streams. Therefore, the best available data do not indicate that disease or predation is a threat to the Black Warrior waterdog.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Under this factor, we examine whether existing regulatory mechanisms are inadequate to address the threats to the Black Warrior waterdog discussed under other factors. Section 4(b)(1)(A) of the Act requires the Service to take into account, ''those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species.'' In relation to Factor D under the Act, we interpret this language to require the Service to consider relevant Federal, State, and Tribal laws and regulations, and other such mechanisms that may minimize any of the threats we describe in threat analyses under the other four factors, or otherwise enhance conservation of the species. We give strongest weight to statutes and their implementing regulations and to management direction that stems from those laws and regulations. An example would be State governmental actions enforced under a State statute or constitution, or Federal action under statute.

The Federal Surface Mining Control and Reclamation Act of 1977, as amended December 22, 1987, requires all permitted mining operations to minimize disturbances and adverse impacts to fish, wildlife, and related environmental values, as well as implement enhancement measures where practicable. It further recognizes the importance of land and water resources restoration as a high priority in reclamation planning. The continued decline of many species, including the flattened musk turtle, fish, and a number of mussels in the Black Warrior Basin (Dodd *et al.* 1988, pp. 55–61; Mettee *et al.* 1989, pp. 12–13; Hartfield 1990, pp. 1–8; Bailey and Guyer 1998, pp. 77–83; Service 2000, pp. 12–13), is often attributed to mining activities, even though this law in effect.

The Alabama Department of Conservation and Natural Resources (ADCNR) recently added the Black Warrior waterdog to its list of non-game State protected species (ADCNR 2012, pp. 1–4). Although this change will make it more difficult to obtain a collecting permit for the species, it does not offer any additional protection for habitat loss and degradation. The ADCNR also recognizes the Black Warrior waterdog as a Priority 2 species of high conservation concern in its State Wildlife Action Plan due to its rarity and restricted distribution (ADCNR 2005, p. 298). However, this designation also does not offer any regulatory protections.

Stream segments within the Black Warrior River drainage currently occupied by the Black Warrior waterdog have been assigned water-use classifications of fish and wildlife (F&W) by the Alabama Department of Environmental Management (ADEM) under the authority of the Clean Water Act of 1972. The F&W designation establishes minimum water quality standards that are believed to be protective of aquatic species. In the Locust Fork, Mulberry Fork, and other tributaries of the Black Warrior River occupied by the Black Warrior waterdog, a combined total of 275 km (171 mi) have been identified on the Alabama 303(d) List (a list of water bodies failing to meet their designated water-use classifications) as impaired by siltation and nutrients (ADEM 2010, pp. 1–3). The sources of these impairments have been identified as runoff from agricultural fields, abandoned surface mines, and industrial or municipal sites. Multiple stream reaches within the occupied habitat of the Black Warrior waterdog (Locust Fork, Mulberry Fork, Yellow Creek, and North River) fail to meet current regulatory standards.

Similarly, even with current regulations, surviving populations are negatively affected by discharges, highway construction, mining (current and unreclaimed sites), and other activities with a Federal nexus (see discussion under *Factor A,* above).

Summary of Factor D

Black Warrior waterdogs and their habitats are partially protected by Federal and State laws and regulations. However, after evaluating the information available on the implementation of these authorities, we determined that these regulatory mechanisms do not address the threats to the species.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

The remaining Black Warrior waterdog populations are isolated from each other by unsuitable habitat created by impoundments, pollution, and other factors as described under the *Factor A* discussion, above. Waterdog population densities are low even in the best localities, and factors related to low population compound these threats.

Inbreeding

Species that are restricted in range and population size are more likely to suffer loss of genetic diversity due to genetic drift, potentially increasing their susceptibility to inbreeding depression, decreasing their ability to adapt to environmental changes, and reducing the fitness of individuals (Soule 1980, pp. 157–158; Hunter 2002, pp. 97–101; Allendorf and Luikart 2007, pp. 117–146). It is likely that some of the Black Warrior waterdog populations are below the effective population size required to maintain long-term genetic and population viability (Soule 1980, pp. 162–164; Hunter 2002, pp. 105–107). The long-term viability of a species is based on the conservation of numerous local populations throughout its geographic range (Harris 1984, pp. 93–104). These separate populations are essential for the species to recover and adapt to environmental change (Noss and Cooperrider 1994, pp. 264–297; Harris 1984, pp. 93–104). The level of isolation and fragmentation seen in this species makes natural repopulation following localized extirpations virtually impossible without human intervention.

Drought

Droughts cause decreases in water flow and dissolved oxygen levels and increases in temperature in the river system. Studies of other aquatic salamander species have reported decreased occupancy, loss of eggs, decreased egg-laying, and extirpation from sites during periods of drought (Camp *et al.* 2000, p. 166; Miller *et al.* 2007, pp. 82–83; Price *et al.* 2012b, pp. 317–319).

Spills

Associated with urbanization is the development of transportation system, including roads, rails, airports, locks, and docks. Accidents, crashes, and derailments, resulting in spills, occur along these transportation corridors. Since 1990, there have been over 1,200 spills reported, to the U.S. Coast Guard National Response Center, in the Basin area. One of several spills that have occurred in the Blackwater Basin was an event in the Black Warrior River in 2013. Approximately 164 gallons of crude oil were accidently pumped into the river. Emergency response teams cleaned the river, but a sheen of crude oil remained visible (Taylor 2013, pers. comm.) (*http://www.tuscaloosanews.com/article/20130617/NEWS/130619792*). Today, the threat from spills remains unchanged.

Climate Change

Our analyses under the Act include consideration of ongoing and projected changes in climate.

According to the IPCC (2013, p. 4), ''Warming of the climate system is unequivocal, and since the 1950s, many of the observed changes are unprecedented over decades to millennia. The atmosphere and ocean have warmed, the amounts of snow and ice have diminished, sea level has risen, and the concentrations of greenhouse gases have increased.'' Average Northern Hemisphere temperatures during the second half of the 20th century were very likely higher than during any other 50-year period in the last 500 years and likely the highest in at least the past 1,300 years (IPCC 2007b, p. 1). It is very likely that from 1950 to 2012, cold days and nights have become less frequent and hot days and hot nights have become more frequent on a global scale (IPCC 2013, p. 4). It is likely that the frequency and intensity of heavy precipitation events has increased over North America (IPCC 2013, p. 4).

The IPCC (2013, pp. 15–16) predicts that changes in the global climate system during the 21st century are very likely to be larger than those observed during the 20th century. For the next two decades (2016 to 2035), a warming of 0.3 degrees Celsius (°C) (0.5 degrees Fahrenheit (°F)) to 0.7 °C (1.3 °F) per decade is projected (IPCC 2013, p. 15). Afterwards, temperature projections increasingly depend on specific emission scenarios (IPCC 2007b, p. 6). Various emissions scenarios suggest that by the end of the 21st century, average global temperatures are expected to increase 0.3 °C to 4.8 °C (0.5 °F to 8.6 °F), relative to 1986 to 2005 (IPCC 2013, p. 15). By the end of 2100, it is virtually certain that there will be more frequent hot and fewer cold temperature extremes over most land areas on daily and seasonal timescales, and it is very likely that heat waves and extreme precipitation events will occur with a higher frequency and intensity (IPCC 2013, pp. 15–16).

Climate change has the potential to increase the vulnerability of the Black Warrior waterdog to random catastrophic events (*e.g.,* McLaughlin *et al.* 2002; Thomas *et al.* 2004). Climate change is expected to result in increased frequency and duration of droughts and the strength of storms (*e.g.,* Cook *et al.* 2004). Thomas *et al.* (2009, p. 112) report that the frequency, duration, and intensity of droughts are likely to increase in the Southeast as a result of global climate change.

Summary of Factor E

We consider the Black Warrior waterdog vulnerable to other natural or manmade factors, because low population densities combined with fragmentation of habitat renders the Black Warrior waterdog populations extremely vulnerable to inbreeding depression (negative genetic effects of small populations) (Wright *et al.* 2008, p. 833) and catastrophic events such as flood, drought, or chemical spills (Black Warrior River Watershed Management Plan n.d., p. 4.4).

Cumulative Effects of Threats

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Black Warrior waterdog. Threats to the remaining Black Warrior waterdog populations exist primarily from two of the five threat factors (Factors A and E), and existing laws and regulations provide only minimal protection against habitat loss (Factor D). Threats also occur in combination, resulting in synergistically greater effects. For instance, in combination with the other threats identified in this proposed rule, a catastrophic hazardous materials spill could increase the species' risk of extinction by reducing its overall probability of persistence. Therefore, we consider hazardous material spills to be an ongoing significant threat to the Black Warrior waterdog due to the species' limited distribution, the abundance of potential sources of spills, and the number of salamanders that could be killed during a single spill event (Factor E).

Proposed Determination

The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' We find that the Black Warrior waterdog is presently in danger of extinction throughout its entire range based on the severity and immediacy of threats currently impacting the species. The overall range has been significantly reduced, and the remaining habitat and populations face threats from a variety of factors (Factors A and E) acting in combination to reduce the overall viability of the species. The risks of extinction are high because the remaining populations are small, isolated, and have limited potential for recolonization (Factor E). Therefore, on the basis of the best available scientific and commercial information, we propose to list the Black Warrior waterdog as an endangered species in accordance with sections 3(6) and 4(a)(1) of the Act.

We find that a threatened species status is not appropriate for the Black Warrior waterdog because of the species' contracted range, loss of habitat due to water quality degradation (sedimentation, toxins, and nutrients), fragmentation of the populations caused by impoundments, rangewide (not localized) threats, and ongoing threats expected to continue into the future.

Significant Portion of the Range

Under the Act and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. Because we have determined that Black Warrior waterdog is endangered throughout all of its range, no portion of its range can be ''significant'' for purposes of the definitions of ''endangered species'' and ''threatened species.'' See the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578, July 1, 2014).

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing actions results in public awareness and conservation by Federal, State, Tribal, and local agencies; private organizations; and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species'

decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline, shortly after a species is listed, and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for downlisting or delisting, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. If this species is listed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our Web site (*http://www.fws.gov/endangered*), or from our Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of Alabama would be eligible for Federal funds to implement management actions that promote the protection or recovery of the Black Warrior waterdog. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the Black Warrior waterdog is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the Service, U.S. Forest Service, and Bureau of Land Management; issuance of section 404 Clean Water Act permits by the U.S. Army Corps of Engineers; construction and maintenance of gas pipeline and power line rights-of-way by the Federal Energy Regulatory Commission; construction and maintenance of roads or highways by the Federal Highway Administration; land management practices supported by programs administered by the U.S. Department of Agriculture; Environmental Protection Agency pesticide registration; and projects funded through Federal loan programs which include, but are not limited to, roads and bridges, utilities, recreation sites, and other forms of development.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered wildlife. The prohibitions of section 9(a)(1) of the Act, codified at 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) endangered wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any listed species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22. With regard to endangered wildlife, a permit may be issued for scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of species proposed for listing. Based on the best available information, the following actions are unlikely to result in a violation of section 9, if these activities are carried out in accordance with existing regulations and permit requirements; this list is not comprehensive:

(1) Normal agricultural and silvicultural practices, including herbicide and pesticide use, which are carried out in accordance with any existing regulations, permit, and label requirements, and best management practices; and

(2) Normal residential development and landscape activities, which are carried out in accordance with any existing regulations, permit

requirements, and best management practices.

Based on the best available information, the following activities may potentially result in a violation of section 9 the Act; this list is not comprehensive:

(1) Unauthorized introduction of nonnative species that compete with or prey upon the Black Warrior waterdog;

(2) Unauthorized collecting, handling, possessing, selling, delivering, carrying, or transporting of the species, including import or export across State lines and international boundaries, except for properly documented antique specimens of this taxa, as defined by section 10(h)(1) of the Act;

(3) Unauthorized destruction or alteration of Black Warrior waterdog habitat that results in destruction or loss of leaf packs and rocky substrate (rock crevices in the creek or stream);

(4) Unauthorized discharge of chemicals or fill material into any waters in which the Black Warrior waterdog is known to occur; and

(5) Actions, intentional or otherwise, that would result in the destruction of eggs or cause mortality or injury to hatchling, juvenile, or adult Black Warrior waterdogs.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Section 4(a)(3) of the Act requires the Secretary, at the time a species is listed as endangered or threatened, to designate critical habitat to the maximum extent prudent and determinable. Elsewhere in this issue of the **Federal Register**, we propose to designate critical habitat for the Black Warrior waterdog.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of references cited in this proposed rule is available on the Internet at *http://www.regulations.gov* and upon request from the Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Alabama Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by adding an entry for ''Waterdog, Black Warrior'' to the List of Endangered and Threatened Wildlife in alphabetical order under AMPHIBIANS to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
AMPHIBIANS				
*	*	*	*	*
Waterdog, Black Warrior	*Necturus alabamensis*	Wherever found	E	[**Federal Register** citation of the final rule]
*	*	*	*	*

Dated: September 26, 2016.

Stephen Guertin

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2016–24119 Filed 10–5–16; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register

Vol. 81, No. 194

Thursday, October 6, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Meeting Notice of the National Agricultural Research, Extension, Education, and Economics Advisory Board

AGENCY: Research, Education, and Economics, USDA.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App 2, Section 1408 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3123), and the Agricultural Act of 2014, the United States Department of Agriculture (USDA) announces a meeting of the National Agricultural Research, Extension, Education, and Economics Advisory Board.

DATES: October 19–21, 2016. The public may file written comments before or up to November 4, 2016.

ADDRESSES: The Lory Student Center at Colorado State University, 1101 Center Avenue Mall, The Grey Rock Room, Fort Collins, Colorado.

Written comments may be sent to: The National Agricultural Research, Extension, Education, and Economics Advisory Board Office, Room 332A, Whitten Building, United States Department of Agriculture, STOP 0321, 1400 Independence Avenue SW., Washington, DC 20250–0321.

FOR FURTHER INFORMATION CONTACT: Michele Esch, Executive Director/Designated Federal Official, or Shirley Morgan-Jordan, Program Support Coordinator, National Agricultural Research, Extension, Education, and Economics Advisory Board; telephone: (202) 720–3684; fax: (202)720–6199; or email: *nareee@ars.usda.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the meeting: To provide advice and recommendations on the top priorities and policies for food and agricultural research, education, extension, and economics. The main focus of this meeting will be on the review of the relevance and adequacy of the climate and energy needs programs of the USDA Research, Education, and Extension mission area. The Board will also receive updates and information pertinent to the research, education, and economics activities in USDA. A detailed agenda may be received from the contact person identified in this notice or at *https://nareeeab.ree.usda.gov/meetings/general-meetings.*

Tentative Agenda: On Wednesday, October 19, 2016, an orientation session for new members and interested incumbent members will be held from 9:00 a.m. MDT–12:00 (noon) p.m. MDT. The full Advisory Board will convene at 12:00 p.m. (noon) MDT and end by 6:00 p.m. MDT.

On Thursday, October 20, 2016, the full Advisory Board will convene at 8:30 a.m. MDT. The Board will depart for a tour to the Grasslands Range Experiment Station at 12:30 p.m. MDT and return to Fort Collins at 5:00 p.m. MDT.

On Friday, October 21, 2016, the Board will reconvene at 8:00 a.m. MDT and will adjourn by 12:00 p.m. (noon) MDT.

Public Participation: This meeting is open to the public and any interested individuals wishing to attend. Opportunity for public comment will be offered each day of the meeting. To attend the meeting and/or make oral statements regarding any items on the agenda, you must contact Michele Esch or Shirley Morgan-Jordan at 202–720–3684; email: *nareee@ars.usda.gov* at least 5 business days prior to the meeting. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. The Chair will conduct the meeting to facilitate the orderly conduct of business. Written comments by attendees or other interested stakeholders will be welcomed for the public record before and up to two weeks following the Board meeting (or by close of business Friday, November 4, 2016). All written statements must be sent to Michele Esch, Designated Federal Officer and Executive Director, National Agricultural Research, Extension, Education, and Economics Advisory Board, U.S. Department of Agriculture, Room 332A, Jamie L. Whitten Building, Mail Stop 0321,1400 Independence Avenue SW., Washington, DC 20250–0321; or email: *nareee@ars.usda.gov.* All statements will become a part of the official record of the National Agricultural Research, Extension, Education, and Economics Advisory Board and will be kept on file for public review in the Research, Education, and Economics Advisory Board Office.

Done at Washington, DC this 28th day of September 2016.

Ann Bartuska,

Deputy Under Secretary, Research, Education, and Economics.

[FR Doc. 2016–24235 Filed 10–5–16; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Forest Service

Sabine-Angelina Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Sabine-Angelina Resource Advisory Committee (RAC) will meet in Hemphill, Texas. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://cloudapps-usda-gov.force.com/FSSRS/RAC_Page?id=001t0000002JcvCAAS.*

DATES: The meeting will be held on Thursday, November 3, 2016, at 3:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at Sabine Ranger District, 5050 State Highway 21 East, Hemphill, Texas.

Written comments may be submitted as described under **SUPPLEMENTARY**

INFORMATION. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Sabine Ranger District. Please call ahead at 409–625–1940 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Becky Nix, RAC Coordinator,by phone at 409–625–1940 or via email at *bnix@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Approve minutes from August 18, 2016 meeting; and
2. Discuss, recommend, and approve new projects.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by Friday, October 28, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Becky Nix, RAC Coordinator, Sabine-Angelina Resource Advisory Committee, 5050 State Highway 21 E, Hemphill, Texas 75948; by email to *bnix@fs.fed.us*, or via facsimile to 409–625–1953.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: September 29, 2016.

James T. Sowell,

Proxy Designated Federal Officer, Sabine-Angelina RAC.

[FR Doc. 2016–24190 Filed 10–5–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Notice and Opportunity for Public Comment.

Pursuant to Section 251 of the Trade Act 1974, as amended (19 U.S.C. 2341 *et seq.*), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of these firms contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[9/24/2016 through 9/30/2016]

Firm name	Firm address	Date accepted for investigation	Product(s)
Northern Crescent Iron, Inc	16 Kay Road, Flat Rock, NC 28731.	9/28/2016	The firm produces knives, bottle openers, cabinet & door hardware and custom ironwork.
Dynamic Design and Manufacturing, Inc.	6321 Monarch Park Place, Niwot, CO 80503.	9/29/2016	The firm manufactures metal mountings, fittings, and similar components for use in a wide range of industries.
Lovell Designs, Inc	26 Exchange Street Portland, ME 4101.	9/29/2016	The firm manufactures cast jewelry and ornaments.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance for Firms Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Miriam Kearse,

Lead Program Analyst.

[FR Doc. 2016–24151 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Russell Henderson Marshall, Currently Incarcerated at: Inmate Number—96646–004, McCrae, Correctional Institution, P.O. Drawer 55030, McCrae Helena, GA 31055, and With an Address at: 14883 64th CT, North Loxahatchee, FL 33470; Order Denying Export Privileges.

On April 24, 2015, in the U.S. District Court for the Southern District of Florida, Russell Henderson Marshall (''Marshall'') was convicted of violating the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.* (2012)) (''IEEPA''). Specifically, Marshall was convicted of violating IEEPA and a U.S. Department of Commerce denial order by engaging in

negotiations concerning selling, delivering, or otherwise servicing transactions involving items exported from the United States and subject to the Regulations, to wit: Three temperature transmitters used on F–16 fighter jets to Thailand, and a saddle part for the J–69 engine used on 737 military trainer aircraft to Pakistan. Marshall was sentenced to 41 months of imprisonment, two years of supervised release, a $200 assessment and ordered to surrender to U.S. Immigration and Customs Enforcement for removal from the United States upon completion of incarceration.

Section 766.25 of the Export Administration Regulations (''EAR'' or ''Regulations'' [1] provides, in pertinent part, that ''[t]he Director of the Office of Exporter Services, in consultation with the Director of the Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of the Export Administration Act (''EAA''), the EAR, or any order, license or authorization issued thereunder; any regulation, license, or order issued under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706); 18 U.S.C. 793, 794 or 798; section 4(b) of the Internal Security Act of 1950 (50 U.S.C. 783(b)), or section 38 of the Arms Export Control Act (22 U.S.C. 2778).'' 15 CFR 766.25(a); *see also* Section 11(h) of the EAA, 50 U.S.C. 4610(h). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d); *see also* 50 U.S.C. 4610(h). In addition, Section 750.8 of the Regulations states that the Bureau of Industry and Security's Office of Exporter Services may revoke any Bureau of Industry and Security (''BIS'') licenses previously issued in which the person had an interest in at the time of his conviction.

BIS has received notice of Marshall's conviction for violating IEEPA, and in accordance with Section 766.25 of the Regulations, BIS has provided notice and an opportunity for Marshall to make a written submission to BIS. BIS has not received a submission from Marshall.

Based upon my review and consultations with BIS's Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Marshall's export privileges under the Regulations for a period of 10 years from the date of Marshall's conviction. I have also decided to revoke all licenses issued pursuant to the Act or Regulations in which Marshall had an interest at the time of his conviction.

Accordingly, it is hereby ordered:

First, from the date of this Order until April 24, 2025, Russell Henderson Marshall, currently incarcerated at: Inmate Number—96646–004, McCrae, Correctional Institution, P.O. Drawer 55030, McCrae Helena, GA 31055, and with a last known address of 14883 64th CT, North Loxahatchee, FL 33470, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (the ''Denied Person''), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Marshall by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Marshall may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to the Marshall. This Order shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until April 24, 2025.

Dated: September 30, 2016.

Thomas Ankrukonis,

Acting Director, Office of Exporter Services.

[FR Doc. 2016–24175 Filed 10–5–16; 8:45 am]

BILLING CODE P

[1] 50 U.S.C. 4601–4623 (Supp. III 2015) (available at *http://uscode.house.gov*). Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 4, 2016 (81 FR 52,587 (Aug. 8, 2016)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.* (2012)).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–826]

Certain Paper Clips From the People's Republic of China: Final Results of Expedited Fourth Sunset Review of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this sunset review, the Department of Commerce (the Department) finds that revocation of the antidumping duty order on certain paper clips (paper clips) from the People's Republic of China (PRC) would be likely to lead to continuation or recurrence of dumping at the levels identified in the ''Final Results of Review'' section of this notice.

DATES: Effective September 29, 2016.

FOR FURTHER INFORMATION CONTACT: Maliha Khan, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0895.

SUPPLEMENTARY INFORMATION: On November 25, 1994, the Department published the notice of the antidumping duty order on paper clips from the PRC.[1] On June 1, 2016, the Department published the notice of initiation of the fourth sunset review of the *AD Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On June 16, 2016, the Department received a notice of intent to participate in this review from ACCO Brands USA LLC (ACCO), a domestic interested party, within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] ACCO claimed interested party status under section 771(9)(C) of the Act as a manufacturer in the United States of a domestic like product. On July 1, 2016, the Department received a complete and adequate substantive response from ACCO within 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] The Department received no substantive responses from respondent interested parties. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted an expedited (120-day) sunset review of the *AD Order.*

Scope of the Order

The products covered by the order are certain paper clips, wholly of wire of base metal, whether or not galvanized, whether or not plated with nickel or other base metal (*e.g.,* copper), with a wire diameter between 0.025 inches and 0.075 inches (0.64 to 1.91 millimeters), regardless of physical configuration, except as specifically excluded. The products subject to the order may have a rectangular or ring-like shape and include, but are not limited to, clips commercially referred to as No. 1 clips, No. 3 clips, Jumbo or Giant clips, Gem clips, Frictioned clips, Perfect Gems, Marcel Gems, Universal clips, Nifty clips, Peerless clips, Ring clips, and Glide-On clips. The products subject to the order are currently classifiable under subheading 8305.90.3010 of the Harmonized Tariff Schedule of the United States (HTSUS).

Specifically excluded from the scope of the order are plastic and vinyl covered paper clips, butterfly clips, binder clips, or other paper fasteners that are not made wholly of wire of base metal and are covered under a separate subheading of the HTSUS.

Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Analysis of Comments Received

A complete discussion of all issues raised in this review, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *AD Order* and the magnitude of the margins likely to prevail if the order were revoked, is provided in the accompanying Issues and Decision Memorandum,[5] which is hereby adopted by this notice. The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, the Department determines that revocation of the *AD Order* would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average margins up to 126.94 percent.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, 19 CFR 351.218, and 19 CFR 351.221(c)(5)(ii).

Dated: September 29, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. History of the Order
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margins Likely To Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2016–24245 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Antidumping Duty Order: Certain Paper Clips From the People's Republic of China,* 59 FR 60606 (November 25, 1994) (*AD Order*).

[2] *See Initiation of Five-Year (''Sunset'') Review,* 81 FR 34974 (June 1, 2016).

[3] *See* Letter from ACCO to the Department, ''Paper Clips from the People's Republic of China: Five-Year (''Sunset'') Review of Antidumping Duty Order (4th Review): Notice of Intent to Participate'' (June 16, 2016).

[4] *See* Letter from ACCO to the Department, ''Paper Clips from the People's Republic of China: Five-Year Review of Antidumping Duty Order (4th Sunset Review), Case No. A–570–826; Substantive Response of ACCO Brands USA LLC'' (July 1, 2016).

[5] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Issues and Decision Memorandum for the Expedited Sunset Review of the Antidumping Duty Order on Paper Clips from the People's Republic of China,'' dated concurrently with this notice (Issues and Decision Memorandum).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–827]

Certain Cased Pencils From the People's Republic of China: Final Results of Expedited Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) finds that revocation of the antidumping duty order (AD) order on certain cased pencils from the People's Republic of China (PRC) would be likely to lead to continuation or recurrence of dumping at the level indicated in the ''Final Results of Review'' section of this notice.

DATES: Effective October 6, 2016.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg, Office I, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1785.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2016, the Department initiated a sunset review of the *AD Order* [1] on certain cased pencils from the PRC pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] The Dixon Ticonderoga Company (Dixon), as well as the General Pencil Co., Inc., Musgrave Pencil Co., and RoseMoon, Inc., notified the Department of their intent to participate in the sunset review as domestic interested parties on June 7, 2016, and June 14, 2016, respectively, pursuant to 19 CFR 351.218(d)(1)(i).[3] Each of these companies claimed interested party status under section 771(9)(C) of the Act, as domestic producers of the domestic like product.

On July 1, 2016, the Department received a collective substantive response from General Pencil Co., Inc., Musgrave Pencil Co., and RoseMoon, Inc., within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] The Department did not receive a substantive response from Dixon or any respondent interested party to the sunset proceeding. Because the Department received no response from the respondent interested parties, the Department conducted an expedited review of this *AD Order,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(l)(ii)(C)(2).

Scope of the Order

Imports covered by the order are shipments of certain cased pencils of any shape or dimension (except as described below) which are writing and/or drawing instruments that feature cores of graphite or other materials, encased in wood and/or man-made materials, whether or not decorated and whether or not tipped (*e.g.,* with erasers, *etc.*) in any fashion, and either sharpened or unsharpened. The pencils subject to the order are currently classifiable under subheading 9609.10.00 of the Harmonized Tariff Schedule of the United States ('HTSUS'). Specifically excluded from the scope of the order are mechanical pencils, cosmetic pencils, pens, noncased crayons (wax), pastels, charcoals, chalks, and pencils produced under U.S. patent number 6,217,242, from paper infused with scents by the means covered in the above-referenced patent, thereby having odors distinct from those that may emanate from pencils lacking the scent infusion. Also excluded from the scope of the order are pencils with all of the following physical characteristics: (1) Length: 13.5 or more inches; (2) sheath diameter: not less than one-and-one quarter inches at any point (before sharpening); and (3) core length: Not more than 15 percent of the length of the pencil. In addition, pencils with all of the following physical characteristics are excluded from the scope of the order: Novelty jumbo pencils that are octagonal in shape, approximately ten inches long, one inch in diameter before sharpening, and three-and-one eighth inches circumference, composed of turned wood encasing one-and-one half inches of sharpened lead on one end and a rubber eraser on the other end. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Analysis of Comments Received

All issues raised in this review are addressed in the Issues and Decision Memorandum, which is dated concurrently with this notice.[5] The issues discussed in the Issues and Decision Memorandum include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the *AD Order* were revoked. Parties can find a complete discussion of all issues raised in this expedited sunset review and the corresponding recommendations in this public memorandum, which is on file electronically *via* the Enforcement and Compliance Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, room B8024 of the main Department of Commerce building. A list of topics discussed in the Issues and Decision Memorandum is included as an Appendix to this notice. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

Final Results of Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, we determine that revocation of the *AD Order* on certain cased pencils from the PRC would be likely to lead to continuation or recurrence of dumping at weighted-average percent margins up to 53.65 percent.

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return/destruction of APO materials or

[1] *See Antidumping Duty Order: Certain Cased Pencils from the People's Republic of China,* 59 FR 66909 (December 28, 1994) (*AD Order*).

[2] *See Initiation of Five-Year (''Sunset'') Review,* 81 FR 34974 (June 1, 2016).

[3] *See* letter from Dixon to the Department, re: ''Five-Year Sunset Review of Certain Cased Pencils from the People's Republic of China: Dixon Notice of Intent to Participate,'' dated June 7, 2016; *see also* letter from General Pencil Co., Inc., Musgrave Pencil Co. and RoseMoon, Inc., to the Department, re: ''§ 751(c) Five-Year Sunset Review of the Antidumping Duty Order Against Cased Pencils from the People's Republic of China; Notice of Appearance and Intent to Participate,'' dated June 14, 2016.

[4] *See* letter from General Pencil Co., Inc., Musgrave Pencil Co. and RoseMoon, Inc. to the Department, re: ''§ 751(c) Five-Year Sunset Review of the Antidumping Duty Order Against Cased Pencils from the People's Republic of China; Substantive Response of Domestic Interested Parties,'' dated July 1, 2016.

[5] *See* Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Issues and Decision Memorandum for the Final Results of the Expedited Five-Year Sunset Review of the Antidumping Duty Order on Certain Cased Pencils from the People's Republic of China,'' dated September 29, 2016.

conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: September 29, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. History of the Order
III. Background
IV. Scope of the Order
V. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margins Likely To Prevail
VI. Final Results of Review
VII. Recommendation

[FR Doc. 2016–24248 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Renewable Energy and Energy Efficiency Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The Renewable Energy and Energy Efficiency Advisory Committee (REEEAC) will hold a meeting on Thursday, December 1, 2016 at the U.S. Department of Commerce Herbert C. Hoover Building in Washington, DC. The meeting is open to the public with registration instructions provided below.

DATES: December 1, 2016, from approximately 8:30 a.m. to 5:00 p.m. Eastern Standard Time (EST). Members of the public wishing to participate must register in advance with Victoria Gunderson at the contact information below by 5:00 p.m. EST on Friday, November 24, 2016, in order to pre-register, including any requests to make comments during the meeting or for accommodations or auxiliary aids.

FOR ALL FURTHER INFORMATION, PLEASE CONTACT: Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries (OEEI), International Trade Administration, U.S. Department of Commerce at (202) 482–7890; email: *Victoria.Gunderson@trade.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Secretary of Commerce established the REEEAC pursuant to discretionary authority and in accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. App.), on July 14, 2010. The REEEAC was re-chartered on June 18, 2012, June 12, 2014, and June 9, 2016. The REEEAC provides the Secretary of Commerce with consensus advice from the private sector on the development and administration of programs and policies to enhance the export competitiveness of the U.S. renewable energy and energy efficiency industries.

During the December 1st meeting of the REEEAC, committee members will hold the first meeting of its new charter term and discuss REEEAC operational structure, hear from Department of Commerce officials and interagency partners on major issues impacting the competitiveness of the U.S. renewable energy and energy efficiency industries, recommend the Sub-Committee structure, and select their recommendations for Committee Chair and Sub-Committee leadership.

The meeting will be open to the public and will be accessible to people with disabilities. All guests are required to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted, but may be impossible to fill.

A limited amount of time before the close of the meeting will be available for pertinent oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two to five minutes per person (depending on number of public participants). Individuals wishing to reserve speaking time during the meeting must contact Ms. Gunderson and submit a brief statement of the general nature of the comments, as well as the name and address of the proposed participant by 5:00 p.m. EST on Monday, November 21, 2016. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a copy of their oral comments by email to Ms. Gunderson for distribution to the participants in advance of the meeting.

Any member of the public may submit pertinent written comments concerning the REEEAC's affairs at any time before or after the meeting. Comments may be submitted to the Renewable Energy and Energy Efficiency Advisory Committee, c/o: Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries, U.S. Department of Commerce; 1401 Constitution Avenue NW.; Mail Stop: 4053; Washington, DC 20230. To be considered during the meeting, written comments must be received no later than 5:00 p.m. EST on Monday, November 21, 2016, to ensure transmission to the Committee prior to the meeting. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of RE&EEAC meeting minutes will be available within 30 days following the meeting.

Dated: October 3, 2016.

Edward A. O'Malley,

Director, Office of Energy and Environmental Industries.

[FR Doc. 2016–24252 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Electronic Monitoring Systems for Atlantic Highly Migratory Species (HMS) Fisheries.

OMB Control Number: 0648–0372.

Form Number(s): None.

Type of Request: Regular (revision and extension of a currently approved information collection).

Number of Respondents: 194.

Average Hours per Response: Four hours for initial VMS installation; 5 minutes per VMS initial activation checklist; 2 minutes per VMS hail-out/hail-in declaration; 6 hours for electronic monitoring installation; 5 minutes for VMS pelagic longline bluefin tuna catch reporting; 15 minutes for VMS purse seine bluefin tuna catch records; 1 minute for dockside review of bluefin tuna catch records previously

submitted via VMS; 2 hours for electronic monitoring data retrieval.

Burden Hours: 6,420.

Needs and Uses: This request is for revision and extension of a currently approved information collection.

VMS and electronic monitoring systems collect important information on fishing effort, catch, and the geographic location of fishing effort and catch for certain sectors of the Atlantic HMS fleet. Data collected through these programs are used in both domestic and international fisheries management, including for law enforcement, stock assessments, and quota management purposes. Atlantic HMS vessels required to use VMS are pelagic longline, purse seine, bottom longline (directed shark permit holders in North Carolina, South Carolina, and Virginia), and gillnet (directed shark permit holders consistent with the requirements of the Atlantic large whale take reduction plan requirements at 50 CFR 229.39.(h)) vessels. In addition to VMS, pelagic longline vessels are also required to have electronic monitoring systems to monitor catch and account for bluefin tuna harvest and discards. Revision: NMFS will now pay EM electronic data retrieval and review costs.

The National Marine Fisheries Service (NMFS) Office of Law Enforcement (OLE) monitors fleet adherence to gear- and time-area restrictions with VMS position location data. Gear restricted areas and time-area closures are important tools for Atlantic HMS management that have been implemented to reduce bycatch of juvenile swordfish, sea turtles, and bluefin tuna, among other species. Electronic monitoring data from the pelagic longline fleet includes bluefin tuna discard and harvest information. These data are used by NMFS to accurately monitor bluefin tuna catch by the pelagic longline fleet, to ensure compliance with Individual Bluefin Quota (IBQ) limits and requirements, and to ensure that the Longline category bluefin tuna quota is not over-harvested. VMS reporting of bluefin tuna catch is used to monitor the status of IBQ allocations in real-time. Atlantic HMS fisheries are managed under the dual authority of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) and the Atlantic Tunas Conservation Act (ATCA). Under the MSA, management measures must be consistent with ten National Standards, and fisheries must be managed to maintain optimum yield, rebuild overfished fisheries, and prevent overfishing. Under ATCA, the Secretary of Commerce shall promulgate regulations, as necessary and appropriate, to implement measures adopted by the International Commission for the Conservation of Atlantic Tunas (ICCAT).

Affected Public: Business and other for-profit organizations.

Frequency: Daily and on occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: October 3, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–24207 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Southeast Region Gulf of Mexico Mandatory Shrimp Vessel and Gear Characterization Survey

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted by December 5, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Adam Bailey, National Marine Fisheries Service, Southeast Regional Office, Sustainable Fisheries Division, 263 13th Ave S, St. Petersburg, FL 33701, (727) 824–8305, or *adam.bailey@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a current information collection.

The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) authorizes the Gulf of Mexico Fishery Management Council (Council) to prepare and amend fishery management plans (FMPs) for any fishery in Federal waters under its jurisdiction. NMFS and the Council manage the shrimp fishery in the Federal waters of the Gulf of Mexico (Gulf) under the FMP for the Shrimp Fishery of the Gulf. The regulations for the Gulf Shrimp Vessel and Gear Characterization Form may be found at 50 CFR 622.51(a)(3).

Owners or operators of vessels applying for or renewing a commercial vessel permit for Gulf shrimp must complete an annual Gulf Shrimp Vessel and Gear Characterization Form. NMFS provides the form at the time of permit application and renewal. Compliance with this reporting requirement is required for permit issuance and renewal.

Through this form, NMFS collects census-level information on fishing vessel and gear characteristics in the Gulf shrimp fishery to conduct analyses that will improve management decision-making in this fishery. In addition, these analyses ensure that national goals, objectives, and requirements of the Magnuson-Stevens Act, National Environmental Policy Act, Regulatory Flexibility Act, Endangered Species Act, and Executive Order 12866 are met; and quantify achievement of the performance measures in the NMFS' Operating Plans. This information is vital in assessing the economic, social, and environmental effects of fishery management decisions and regulations on individual shrimp fishing enterprises, fishing communities, and the nation as a whole.

There have been minor adjustments to responses and burden. As of August 26, 2016, there are approximately 1,445 vessels with valid or renewable permits in the Gulf shrimp fishery. The slightly fewer number of vessels has resulted in adjusted estimates of total burden hours and costs as noted below in Section III.

II. Method of Collection

Respondents are mailed hard copies of the form. Permit applicants must complete and mail the form back to

NMFS before permits expire and before NMFS will issue permits.

III. Data

OMB Control Number: 0648–0542.

Form Number(s): None.

Type of Review: Regular submission—renewal of a current information collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,445.

Estimated Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 482.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: October 3, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–24194 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE933

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Herring Committee on Thursday, October 20, 2016 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Thursday, October 20, 2016 at 10 a.m.

ADDRESSES: The meeting will be held at the DoubleTree by Hilton, 363 Maine Mall Road, South Portland, ME 04106; phone: (207) 775–6161; fax: (207) 756–6622.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Herring Committee will discuss next steps for Management Strategy Evaluation of Atlantic Herring Acceptable Biological Catch control rules being considered in Amendment 8 to the Atlantic Herring Fishery Management Plan (FMP), including review of draft goals and agenda for a public workshop. Review additional Plan Development Team analysis and continue development of measures related to localized depletion to be considered in Amendment 8 to the Atlantic Herring FMP. The committee will also review progress and provide input on Framework Adjustment 5 to the Atlantic Herring FMP, an action considering modification of accountability measures (AMs) that trigger if the sub-ACL of Georges Bank haddock is exceeded by the midwater trawl herring fishery. Other business will be discussed as necessary. The Committee will also have a closed session to review 2018–20 Herring Advisory Panel applications and make recommendations for approval to the Council's Executive Committee.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 3, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–24172 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE934

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Charter Implementation Committee will meet telephonically on October 24, 2016.

DATES: The meeting will be held on Monday, October 24, 2016, from 10 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252. Teleconference line is (907) 271–2896.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Steve MacLean, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:

Agenda

Monday, October 24, 2016

The agenda is to identify a range of potential management measures for the Area 2C and Area 3A charter halibut fisheries in 2017, using the management measures in place for 2016 as a baseline. For Area 2C, the baseline management measure is a daily limit of one fish less than or equal to 43 inches or greater than or equal to 80 inches in length. For Area 3A, the baseline management measure is an annual limit of four fish, a daily limit of two fish, one fish of any size, and a second fish which must be 28 inches or less in length and a Wednesday closure. Committee recommendations will be incorporated into an analysis for Council review in December 2016. The Council will recommend preferred management measures for consideration by the International Pacific Halibut

Commission at its January 2017 meeting, for implementation in 2017.

The Agenda is subject to change, and the latest version will be posted at *http://www.npfmc.org/*

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: October 3, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–24170 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Southeast Region Gulf of Mexico Electronic Logbook Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted by December 5, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Adam Bailey, National Marine Fisheries Service, Southeast Regional Office, Sustainable Fisheries Division, 263 13th Ave S, St. Petersburg, FL 33701, (727) 824–8305, or *adam.bailey@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a current information collection.

The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) authorizes the Gulf of Mexico Fishery Management Council (Council) to prepare and amend fishery management plans for any fishery in waters under its jurisdiction. NMFS manages the shrimp fishery in the waters of the Gulf of Mexico (Gulf) under the Fishery Management Plan for the Shrimp Fishery of the Gulf. The electronic logbook (ELB) regulations for the Gulf shrimp fishery may be found at 50 CFR 622.51(a)(2).

As of August 25, 2016, there are approximately 1,445 valid or renewable Federal permits to harvest shrimp from the exclusive economic zone (EEZ) in the Gulf. Monitoring shrimp vessels, operating together with many other fishing vessels of differing sizes, gears types used, and fishing capabilities, is made even more challenging by seasonal variability in shrimp abundance and price, and the broad geographic distribution of the fleet. ELBs provide a precise means of estimating the amount of shrimp fishing effort. Using ELBs to estimate fishing effort serves an important role to help estimate bycatch in the Gulf shrimp fleet.

II. Method of Collection

The current electronic logbook unit automatically collects fishing effort data and transmits those data via a cellular phone connection activated when the vessel is within non-roaming cellular range.

III. Data

OMB Control Number: 0648–0543.

Form Number(s): None.

Type of Review: Regular (extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,445.

Estimated Time per Response: 6 hours.

Estimated Total Annual Burden Hours: 3,132.

Estimated Total Annual Cost to Public: $404,600.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: October 3, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–24195 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Statement of Financial Interests, Regional Fishery Management Councils

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before December 5, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Brian Fredieu, (301) 427–8505 or *brian.fredieu@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for revision and extension of a current information collection. The Magnuson-Stevens

Fishery Conservation and Management Act (Magnuson Stevens Act) authorizes the establishment of Regional Fishery Management Councils to exercise sound judgment in the stewardship of fishery resources through the preparation, monitoring, and revision of such fishery management plans under circumstances (a) which will enable the States, the fishing industry, consumers, environmental organizations, and other interested persons to participate in the development of such plans, and (b) which take into account the social and economic needs of fishermen and dependent communities.

Section 302(j) of the Magnuson-Stevens Act requires that Council members appointed by the Secretary, Scientific and Statistical Committee (SSC) members appointed by a Council under Section 302(g)(1), or individuals nominated by the Governor of a State for possible appointment as a Council member, disclose their financial interest in any Council fishery. These interests include harvesting, processing, lobbying, advocacy, or marketing activity that is being, or will be, undertaken within any fishery over which the Council concerned has jurisdiction, or with respect to an individual or organization with a financial interest in such activity. The authority to require this information and reporting and filing requirements has not changed. Revision: NOAA Fisheries is in the process of conducting minor revisions to the form by adding clearer instructions and clarifying some of the questions asked to ensure the questions are consistent with the regulatory requirements. Revisions will also include a specific check box to indicate that a Council nominee, and not a member, is completing the form.

The Secretary is required to submit an annual report to Congress on action taken by the Secretary and the Councils to implement the disclosure of financial interest and recusal requirements, including identification of any conflict of interest problems with respect to the Councils and SSCs and recommendations for addressing any such problems.

The Act further provides that a member shall not vote on a Council decision that would have a significant and predictable effect on a financial interest if there is a close causal link between the Council decision and an expected and substantially disproportionate benefit to the financial interest of the affected individual relative to the financial interest of other participants in the same gear type or sector of the fishery. However, an affected individual who is declared ineligible to vote on a Council action may participate in Council deliberations relating to the decision after notifying the Council of his/her recusal and identifying the financial interest that would be affected.

II. Method of Collection

Respondents submit paper forms. The forms and related instructions are available to the public on the Internet and can be completed online and printed. Seated Council members appointed by the Secretary, including the Tribal Government appointee and SSC members, must file a financial interest form within 45 days of taking office and must provide updates of their statements at any time any such financial interest is acquired, or substantially changed.

III. Data

OMB Number: 0648–0192.

Form Number: NOAA Form 88–195.

Type of Review: Regular submission (request for revision and extension of a current information collection).

Affected Public: Individuals or households.

Estimated Number of Respondents: 330.

Estimated Time per Response: 45 minutes.

Estimated Total Annual Burden Hours: 247.

Estimated Total Annual Cost to Public: $353.10 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: September 30, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–24193 Filed 10–5–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2016–OS–0005]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by November 7, 2016.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Family Member Travel Screening; DD Form X678 TEST, Screening Verification, DD Form X678–1TEST, Medical and Education Information, DD Form X678–2TEST, Dental Health Information, and DD Form X678–3TEST, Patient Care Review, DD Form X678–4 TEST, Administrative Review Checklist; OMB Control Number 0704–XXXX.

Type of Request: New.

Number of Respondents: 17,943.

Responses per Respondent: 1.

Annual Responses: 17,943.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 4,617 hours.

Needs and Uses: The DD Forms DD Form X678 TEST X678–1 TEST, X678–2 TEST, X678–3 TEST, and DD Form X678–4 TEST are to be used during the Family Member Travel Screening (FMTS) process when active duty Service members with Permanent Change of Station (PCS) orders to OCONUS or remote installations request Command sponsorship for accompanied travel. These forms assist in determining the availability of care at a gaining installation by documenting any special medical, dental, and/or educational needs of dependents accompanying the Service member. Throughout the process, form respondents include: (1) Active duty Service members and/or dependents over the age of majority who provide demographic information; (2) medical and dental providers who provide information about dependent medical and dental needs; (3) losing FMTS Office staff who document any special medical, dental, and/or educational needs; and (4) gaining FMTS Office staff who document the availability of special needs support services at a gaining location.

Affected Public: Individuals or households; medical and dental providers.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Ms. Jasmeet Seehra.

Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 03F09, Alexandria, VA 22350–3100.

Dated: October 3, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–24199 Filed 10–5–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2016–HQ–0005]

Proposed Collection; Comment Request

AGENCY: Commander Navy Installation Command, DoD.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Commander Navy Installation Command (CNIC) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by December 5, 2016.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Commander Navy Installations Command, 716 Sicard Street SE., Suite 1000, Washington Navy Yard, DC 20374–5140, or call the Family Readiness Lead at 202–433–3165.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Navy Ombudsman Registry; DD Form 2793; OMB 0703–XXXX.

Needs and Uses: The information collection requirement is necessary to identify all Navy ombudsmen; provide them with program information; communicate during natural disasters and crisis; collect program contact numbers and workload data; and maintain records of program training received. Numbers provided from the collection help identify the issues and concern of the families, trends during deployment and identify training which may be beneficial to the command families.

Affected Public: Individuals or Households.

Annual Burden Hours: 1,050.

Number of Respondents: 2,100.

Responses per Respondent: 1.

Annual Responses: 2,100.

Average Burden per Response: 30 minutes.

Frequency: Monthly, Quarterly, and on Occasion.

Respondents are the spouses of active duty members of the command or selected reserves of the command. They may also be the parent or family member of a single service member or retired service members of the command that meet certain requirements. The information obtained from the worksheets assists CNIC in identifying resources and/or trainings to assist ombudsmen in supporting and maintaining family readiness, which enables commands to focus on mission readiness. Statistics provided from collection shows commanding officers the issues and concerns of command families, trends during deployment versus non-deployment periods, and training which may be beneficial to the command and families. The worksheet information shows Navy leadership the cost avoidance benefit to the Navy for having ombudsmen perform the types of services that they deliver.

Dated: October 3, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–24188 Filed 10–5–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–2713–000.

Applicants: Public Service Company of New Mexico.

Description: § 205(d) Rate Filing: Filing to Revise Depreciation Rates in

PNM's Transmission Formula Rate to be effective 10/1/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5165.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2714–000.

Applicants: Idaho Power Company.

Description: § 205(d) Rate Filing: Attachment K—2016 Requirement and Process Clarifications to be effective 11/30/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5167.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2715–000.

Applicants: NorthWestern Corporation.

Description: § 205(d) Rate Filing: Northern Tier Transmission Group Attachment K Revisions to be effective 11/30/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5168.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2716–000.

Applicants: NextEra Energy Transmission MidAtlantic, LLC.

Description: Baseline eTariff Filing: NextEra Energy Transmission MidAtlantic, LLC Filing to Establish a Formula Rate to be effective 11/30/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5169.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2717–000.

Applicants: NextEra Energy Transmission Midwest, LLC.

Description: Baseline eTariff Filing: NextEra Energy Transmission Midwest, LLC Filing to Establish a Formula Rate to be effective 11/30/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5170.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2718–000.

Applicants: Portland General Electric Company.

Description: § 205(d) Rate Filing: Att K Update Filing to be effective 11/1/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5180.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2719–000.

Applicants: NextEra Energy Transmission New York, Inc.

Description: Baseline eTariff Filing: NextEra Energy Transmission New York, Inc. Filing to Establish a Formula Rate to be effective 11/30/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5183.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2720–000.

Applicants: NextEra Energy Transmission Southwest, LLC.

Description: Baseline eTariff Filing: NextEra Energy Transmission Southwest, LLC Filing to Establish a Formula Rate to be effective 11/30/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5190.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2721–000.

Applicants: New England Power Pool Participants Committee.

Description: § 205(d) Rate Filing: Oct 2016 Membership Filing to be effective 10/1/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5199.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2722–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: EIM OATT Flexible Ramping Product REvisions to be effective 10/1/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5209.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2723–000.

Applicants: Connecticut Yankee Atomic Power Company.

Description: § 205(d) Rate Filing: Connecticut Yankee Application to Update Decommissioning Estimate to be effective 12/1/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5259.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2724–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: Amendments to Duke Cities NITSAs to be effective 9/1/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5268.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2725–000.

Applicants: PSEG Energy Solutions LLC.

Description: Baseline eTariff Filing: PSEG Energy Solutions LLC Market Based Rate Tariff to be effective 12/1/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5269.

Comments Due: 5 p.m. ET 10/21/16.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES16–56–000.

Applicants: Kingsport Power Company.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Kingsport Power Company.

Filed Date: 9/30/16.

Accession Number: 20160930–5189.

Comments Due: 5 p.m. ET 10/21/16.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH16–15–000.

Applicants: Energy Future Holdings Corp.

Description: Energy Future Holdings Corp. submits FERC 65–B Waiver Notification, *et al.*

Filed Date: 9/30/16.

Accession Number: 20160930–5181.

Comments Due: 5 p.m. ET 10/21/16.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR16–7–000.

Applicants: North American Electric Reliability Corporation.

Description: Petition of North American Electric Reliability Corporation for approval of amendments to the Western Electricity Coordinating Council bylaws.

Filed Date: 9/29/16.

Accession Number: 20160929–5220.

Comments Due: 5 p.m. ET 10/20/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 30, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–24204 Filed 10–5–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2464–011; ER13–1585–010; ER13–1139–016; ER11–2657–010; ER10–2465–009; ER10–2464–011.

Applicants: First Wind Energy Marketing, LLC, Imperial Valley Solar 1,

LLC, Longfellow Wind, LLC, Milford Wind Corridor Phase I, LLC, Milford Wind Corridor Phase II, LLC, Regulus Solar, LLC.

Description: Supplement to June 30, 2016 Market Power Update for the Southwest Region of First Wind Energy Marketing, LLC, *et al.*

Filed Date: 9/29/16.

Accession Number: 20160929–5210.

Comments Due: 5 p.m. ET 10/20/16.

Docket Numbers: ER15–1510–002.

Applicants: FirstEnergy Solutions Corp.

Description: Compliance filing: Compliance to 51 to be effective 11/16/2015.

Filed Date: 9/30/16.

Accession Number: 20160930–5128.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2048–001.

Applicants: Exelon West Medway II, LLC.

Description: Compliance filing: Amended Certificate of Concurrence Filing to be effective 10/1/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5087.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2509–002.

Applicants: Rutherford Farm, LLC.

Description: Tariff Amendment: Additional Amendment to Application and Initial Baseline Tariff Filing to be effective 10/29/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5040.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2566–001.

Applicants: Dynegy Midwest Generation, LLC.

Description: Tariff Amendment: Superseded Revised Rate Schedule to be effective 10/17/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5157.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2698–001.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Errata to Amendment to Service Agreement No. 3153, Queue No. W1–029 to be effective 11/4/2011.

Filed Date: 9/29/16.

Accession Number: 20160929–5175.

Comments Due: 5 p.m. ET 10/20/16.

Docket Numbers: ER16–2703–000.

Applicants: Deerfield Wind Energy, LLC.

Description: Baseline eTariff Filing: Application for MBR Filing to be effective 10/7/2016.

Filed Date: 9/29/16.

Accession Number: 20160929–5174.

Comments Due: 5 p.m. ET 10/20/16.

Docket Numbers: ER16–2704–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: Kitching Street 115 kV Intx Project Wholesale Distribution Load IFA to be effective 10/1/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5002.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2705–000.

Applicants: Orange and Rockland Utilities, Inc.

Description: § 205(d) Rate Filing: Filing of Integrated ESA to be effective 9/30/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5019.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2706–000.

Applicants: Idaho Power Company.

Description: Compliance filing: LGIA/SGIA Modifications—Order Nos. 827 and 828 Combined Compliance Filing to be effective 11/30/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5073.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2707–000.

Applicants: California Independent System Operator Corporation.

Description: Petition for Approval of Disposition of Proceeds of Penalty Assessments and Non-Refundable Interconnection Financial Security of California Independent System Operator Corporation.

Filed Date: 9/29/16.

Accession Number: 20160929–5212.

Comments Due: 5 p.m. ET 10/20/16.

Docket Numbers: ER16–2709–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Service Agreement No. 4489, Queue No. AA1–116/AA1–117 Cancellation to be effective 12/1/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5124.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2710–000.

Applicants: MATL LLP.

Description: § 205(d) Rate Filing: MATL K clean up filing to be effective 11/23/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5133.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2711–000.

Applicants: Talen Energy Marketing, LLC.

Description: § 205(d) Rate Filing: Reactive Revenue Adjustment Filing to be effective 11/17/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5142.

Comments Due: 5 p.m. ET 10/21/16.

Docket Numbers: ER16–2712–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: OATT Revised Attachment K—1st planning cycle modifications to be effective 11/30/2016.

Filed Date: 9/30/16.

Accession Number: 20160930–5162.

Comments Due: 5 p.m. ET 10/21/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 30, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–24203 Filed 10–5–16; 8:45 am]

BILLING CODE 6717–01–P

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board; Sunshine Act; Regular Meeting

AGENCY: Farm Credit Administration.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act, of the regular meeting of the Farm Credit Administration Board (Board).

DATES: The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on October 13, 2016, from 9:00 a.m. until such time as the Board concludes its business.

ADDRESSES: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090. Submit attendance requests via email to *VisitorRequest@FCA.gov.* See **SUPPLEMENTARY INFORMATION** for further information about attendance requests.

FOR FURTHER INFORMATION CONTACT: Dale L. Aultman, Secretary to the Farm Credit Administration Board, (703) 883–4009, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: This meeting of the Board will be open to the

public (limited space available). Please send an email to *VisitorRequest@FCA.gov* at least 24 hours before the meeting. In your email include: name, postal address, entity you are representing (if applicable), and telephone number. You will receive an email confirmation from us. Please be prepared to show a photo identification when you arrive. If you need assistance for accessibility reasons, or if you have any questions, contact Dale L. Aultman, Secretary to the Farm Credit Administration Board, at (703) 883–4009. The matters to be considered at the meeting are:

Open Session

A. Approval of Minutes

- September 8, 2016

B. New Business

- Profit Outlook for the 2016 Corn, Soybean and Wheat Crops

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2016–24296 Filed 10–4–16; 11:15 am]

BILLING CODE 6705–01–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Request for Comment on the Exposure Draft Titled Leases: An Amendment of SFFAS 5, Accounting for Liabilities of the Federal Government and SFFAS 6, Accounting for Property, Plant, and Equipment

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Board Action: Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB Rules Of Procedure, as amended in October 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued an exposure draft titled *Leases: An Amendment of SFFAS 5, Accounting for Liabilities of the Federal Government and SFFAS 6, Accounting for Property, Plant, and Equipment.*

The exposure draft is available on the FASAB Web site at *http://www.fasab.gov/documents-for-comment/*. Copies can be obtained by contacting FASAB at (202) 512–7350.

Respondents are encouraged to comment on any part of the exposure draft. Written comments are requested by January 6, 2017, and should be sent to *fasab@fasab.gov* or Wendy M. Payne, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street NW., Suite 6814, Mail Stop 6H19, Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Ms. Wendy M. Payne, Executive Director, 441 G Street NW., Mail Stop 6H19, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act, Public Law 92–463.

Dated: September 30, 2016.

Wendy M. Payne,

Executive Director.

[FR Doc. 2016–24135 Filed 10–5–16; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Request for Comment on the Exposure Draft Titled Federal Financial Reporting

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Board Action: Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB Rules of Procedure, as amended in October 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued an exposure draft titled *Federal Financial Reporting.*

The exposure draft is available on the FASAB Web site at *http://www.fasab.gov/documents-for-comment/*. Copies can be obtained by contacting FASAB at (202) 512–7350.

Respondents are encouraged to comment on any part of the exposure draft. Written comments are requested by January 6, 2017, and should be sent to *fasab@fasab.gov* or Wendy M. Payne, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street NW., Suite 6814, Mail Stop 6H19, Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Ms. Wendy M. Payne, Executive Director, 441 G Street NW., Mail Stop 6H19, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. 92–463.

Dated: September 30, 2016.

Wendy M. Payne,

Executive Director.

[FR Doc. 2016–24137 Filed 10–5–16; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL COMMUNICATIONS COMMISSION

Privacy Act System of Records.

AGENCY: Federal Communications Commission.

ACTION: Notice; one new Privacy Act system of records; three deleted systems of records.

SUMMARY: The Federal Communication Commission (FCC or Commission, or the Agency) proposes to add one new, consolidated system of records, FCC/OMD–25, Financial Operations Information System (FOIS) to its inventory of records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a) as amended. This action is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of records maintained by the agency (5 U.S.C. 552a(e)(4)). FCC/OMD–25 will consolidate the three system of records, FCC/OMD–6, Financial Accounting Systems (FAS), FCC/OMD–9, Commission Registration System (CORES), and FCC/OMD–19, Denial of Federal Benefits (Drug Debarment List), and also add new and/or updated information that pertains to the mission and activities of the FCC's Financial Operations (FO) organization in the Office of Managing Director, which are associated with the Commission's financial and budgetary operations, programs, activities, and transactions, and the related telecommunications functions. Upon approval of FCC/OMD–25, the Commission will cancel FCC/OMD–6, FCC/OMD–9, and FCC/OMD–19.

DATES: Written comments are due on or before November 7, 2016. This action will become effective on November 15, 2016 unless comments are received that require a contrary determination.

ADDRESSES: Send comments to Leslie F. Smith, Privacy Analyst, Information Technology (IT), Room 1–C216, Federal Communications Commission (FCC), 445 12th Street SW., Washington, DC 20554, (202) 418–0217, or via the Internet at *Leslie.Smith@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Leslie F. Smith, (202) 418–0217, or *Leslie.Smith@fcc.gov,* and to obtain a copy of the Narrative Statement, which includes details of this proposed new system of records.

SUPPLEMENTARY INFORMATION: The FCC previously gave notice of the three systems of records, FCC/OMD–6, Financial Accounting Systems (FAS), FCC/OMD–9, Commission Registration System (CORES), and FCC/OMD–19,

Denial of Federal Benefits (Drug Debarment List), which it intends to cancel upon approval of FCC/OMD–25, Financial Operations Information System (FOIS), by publication in the **Federal Register** on April 5, 2006 (71 FR 17234, 17250, 17253, and 17264 respectively). The Financial Operations Information System (FOIS) consolidates the three separate systems of records: FCC/OMD–6, Financial Accounting Systems (FAS),[1] FCC/OMD–9, Commission Registration System (CORES),[2] and FCC/OMD–19, Denial of Federal Benefits (Drug Debarment List),[3] and extends coverage to all other related FO financial and budgetary information systems, subsystems, databases, records, and paper document files, which include but are not limited to Genesis, Fee Filer, Red Light Display System, Accounts Payable and Accounts Receivable, Research Reconciliation and Reporting, Budget Center, Electronic Form 159/Remittance Over Secure Internet E-Commerce (ROSIE) system, Pay Fees system, Commission Registration System (CORES), Historical Collections system, Historical Loans system, International Telecommunications Settlements invoicing systems, FO-Administration, system-to-system integrations, databases, and related FO documents and forms. This consolidation will create a single, organization-wide, and consistently-defined system of records that also provides various improvements, which include, but are not limited to, increased efficiency in the Commission's reporting capabilities and enhanced reliability and consistency in the Commission's financial and budgetary data and related management and oversight of these telecommunications programs, functions, and activities.

FCC/OMD–25

SYSTEM NAME:

Financial Operations Information System (FOIS).

SECURITY CLASSIFICATION:

The FCC's CIO will develop a security classification to this system of records based on NIST FIPS–199 standards.

SYSTEM LOCATION:

Financial Operations (FO), Office of Managing Director (OMD), Federal Communications Commission (FCC), 445 12th Street SW., Washington, DC 20554.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The categories of individuals in FOIS include, but are not limited to:

1. FCC staff, including but not limited to employees (including interns), and contractors and vendors, who handle information in the FCC's financial and budgetary operations, which include but are not limited to the FO organization's programs, processes, activities, and related telecommunications functions;

2. Individuals who register with the FCC to receive a FCC Registration Number (FRN) to conduct business with the Commission; and

3. Individuals who intend to or do conduct business with the FCC as a regulatee, licensee, contractor, or vendor and who are listed on the Drug Debarment Roster (as a result of drug convictions for the distribution or possession of controlled substances) who have been denied all Federal benefits as part of their sentence pursuant to Section 5301 of the *Anti-Drug Abuse Act of 1988,* and who have filed application(s) for any FCC professional or commercial license(s) and/or authorization(s).

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in the Financial Operations Information System (FOIS) include, but are not limited to information pertaining to:

1. FCC employees (including interns)—individual's name, Social Security Number (SSN), home address, phone number, bank account data, and miscellaneous monies received by the Commission (including, but not limited to reimbursement(s) authorized under the Travel Reimbursement Program covered by the government-wide system of records GSA/GOVT–3 and GSA/GOVT–4,[4] and related financial requirements);

2. Independent contractors—individual's name and Social Security Number (SSN) (required when the fee exceeds the minimum $600.00 threshold authorized by IRS Form 1099);

3. Individuals who register to do business with the FCC and receive a FCC Registration Number (FRN)—individual's name, address(es), Social Security Number (SSN), Individual Taxpayer Identification Number (ITIN), home telephone number(s), personal fax number(s), personal email address(es), records of services rendered, loan payment information, forfeitures assessed and collected, billing and collection of bad checks, bank deposit information, transaction type information, United States Treasury deposit data (notification of completion of FCC financial transactions with the US Treasury), and information substantiating fees collected, refunds issues, and interest, penalties, and administrative charges assessed to individuals.

4. Individuals on the DOJ's Drug Debarment List—individual's name, DOJ identification number (ID) (for the person denied Federal benefits), Individual Taxpayer Identification Number (ITIN), starting and ending date of the denial of Federal benefits, address, zip code, and (if required by the FCC application) birthdate, and confirmation report for DOJ matching; (Upon such a match, the FCC will initiate correspondence with the applicant, which will also be associated with the application. The confirmation report and any correspondence with the applicant will be among the records found in this system.); and

5. FCC Forms which include, but are not limited to, Forms 44 and 45; 159 series; 160 and 161; 1064, and other related financial and/or budgetary forms, assessments, and related documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. Chapter 57; 31 U.S.C. 525, 3302(e); 44 U.S.C. 3101, 3102, 3309; *Debt Collection Act* as amended by the *Debt Collection Improvement Act of 1996;* Section 639 of the *Consolidated Appropriations Act of 2005* (P.L. 108–447); Federal Financial Management Improvement Act of 1996; Chief Financial Officers Act of 1990; Federal Managers Financial Integrity Act of 1982; Executive Order 9397; *Budget and Accounting Act of 1921; Budget and Accounting Procedures Act of 1950;* and *Federal Communications Authorization Act of 1989;* Section 5301 of the *Anti-Drug Abuse Act of 1988* (Pub. L. 100–690), as amended by Section 1002(d) of the *Crime Control Act of 1990* (Pub. L.

[1] FCC/OMD–6, Financial Accounting Systems (FAS), includes the Genesis, Fee Filer, Red Light Display System, Accounts Payable and Accounts Receivable, Research Reconciliation and Reporting, Budget Center, Electronic Form 159/Remittance Over Secure Internet E-Commerce (ROSIE) system, Pay Fees system, Historical Collections system, Historical Loans system, and International Telecommunications Settlements invoicing systems and all these data.

[2] FCC/OMD–9, Commission Registration System (CORES), includes only the Commission Registration System data.

[3] FCC/OMD–19, Denial of Federal Benefits (Drug Debarment List), includes only the Drug Debarment List data.

[4] The PII contained in the FCC's Travel and Reimbursement Program is covered by one or the other of the two government-wide systems of records maintained by the General Services Administration (GSA): GSA/GOV–3, ''Travel Charge Card Program,'' *see* 78 FR 20108; or GSA/GOVT–4, ''Contracted Travel Services Program,'' *see* 64 FR 20108.

100–647); and 47 U.S.C. 154(i) and 154(j).

PURPOSE(S):

The Financial Operations Information System (FOIS) SORN will cover the PII that is collected, used, and stored in the electronic records and paper document files contained in the FO organization's information systems, subsystems, databases, and paper document files,[5] which are associated with the Commission's financial and budgetary operations, programs, functions, and transactions, and related telecommunications activities. These various systems include, but are not limited to Genesis, Fee Filer, Red Light Display System, Accounts Payable and Accounts Receivable, Research Reconciliation and Reporting, Budget Center, Electronic Form 159/Remittance Over Secure Internet E-Commerce (ROSIE) system, Pay Fees system, Commission Registration System (CORES), Historical Collections system, Historical Loans system, International Telecommunications Settlements invoicing systems, FO-Administration, system-to-system integrations, databases, and related FO documents and forms. Authorized FCC personnel (including authorized contract employees and sole proprietors) use these records on a need-to-know basis to conduct the Commission financial and budgetary operations, programs, transactions, and statements, and related telecommunications activities, which include but are not limited to:

1. Processing and tracking payments made and monies owed from or to individuals (including FCC employees and authorized contract employees and authorized sole proprietor contractors), FCC regulatees and licensees, and the FCC, and to ensure that payments by the FCC are based on a lawful official commitment and obligation of government funds, including but not limited to payments to cover administrative charges, penalties, forfeitures assessed, fees collected, services rendered, and direct loans;

2. Establishing records of ''receivables'' and tracking repayment status for any amount(s) claimed in the event of a debt owed to the FCC, which include but are not limited to repayment of overpayments and excess disbursements (including reimbursements and/or refunds for incorrect payments or overpayments), and other debts, advance payments, including but not limited to application processing fees, travel advances (including reimbursements authorized under the Travel Reimbursement Program covered by GSA/GOVT–3 and GSA/GOVT–4),[6] advanced sick leave, and advanced annual leave, and withholding services from individuals who owe delinquent debt to the FCC or an FCC component, including billing and collection of bad checks;

3. Developing reports of taxable income using the records of payments and uncollectible debts that are provided to the Internal Revenue Service (IRS) and applicable state and local taxing officials;

4. Tracking overdue and delinquent federal debts for debt collection purposes;

5. Initiating and completing computer matching to verify benefit and payment eligibility under relevant related Federal Government systems such as, but not limited to Treasury's ''Do Not Pay'' portal verification system, the GSA Excluded Parties and Debarment List, and the Department of Justice Drug Debarment Roster in connection with implementation of Section 5301 of the *Anti-Drug Abuse Act of 1998;*

6. Populating FCC forms, which include but are not limited to Forms 44 and 45, 159 series, 160 and 161, and 1064, and other financial and budgetary forms and related documents and records, which are used to carry out these various financial, accounting, and budgetary activities, functions, and purposes, and related telecommunications activities;

7. Providing the viewing function for images of auction loans that the FCC has made to customers, to provide them access to their loan payment history (retained for historical purposes); and

8. Storing the information that the Department of Justice (DOJ) exchanges with the FCC in connection with the implementation of Section 5301 of the *Anti-Drug Abuse Act of 1988.*[7]

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside the FCC as a routine use pursuant to 5 U.S.C. 552a(b)(3). In each of these cases, however, the FCC will determine whether disclosure of the records is compatible with the purpose(s) for which the records were collected:

1. Public Access—After registering at the CORES Web site at: *http://www.fcc.gov* to obtain their FCC Registration Number (FRN) and a password, individuals can use the Commission's automated reporting tools of Electronic Form 159/ROSIE, Fee Filer, Pay Fees, and the Red Light Display System to conduct business with the FCC, including to access information, which includes but is not limited to Regulatory Fees, fines, forfeitures, penalties, Debt Collection Improvement Act and other administrative changes, and related payments and assessments, and to determine the amount(s) owed.

2. Drug Debarment List—Any report resulting from any matching program activities between a FCC applicant and an individual on the Department of Justice (DOJ) Drug Disbarment List (not including the DOJ ID Number) and any correspondence with the applicant regarding this match will be associated with the applicant's application, and thus, be made routinely available (with redactions for date of birth and Social Security Number) for public inspection as part of the FCC application file.

3. ''Pay.gov'' System—To disclose the name and address of individuals to the Department of the Treasury to facilitate the collection of any fees owed to the FCC when an individual chooses to pay online using the Treasury's Pay.gov system.

4. Audits and Oversight—To disclose information to auditors, officials of the Office of Inspector General, for the purpose of conducting financial or compliance audits.

5. Compliance with Welfare Reform Requirements—Names, Social Security Numbers, home addresses, dates of birth, dates of hire, quarterly earnings, employer identifying information, and state of hire of employees may be disclosed to the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services for the

[5] The FCC's Financial Operations maintains the FCC's Registration Number (FRN) system, the Commission-wide method for identifying and interacting with those individuals who have registered to do business with the FCC under 31 U.S.C. 7701(c)(2) and who incur application and/or regulatory fee obligations. (The FRN collaterally allows that monies paid are properly matched with debts and obligations.)

[6] Travel Reimbursement Program, *Op. cit.*

[7] This permits the FCC to perform the General Services Administration (GSA) Debarment List check as provided for in the Office of National Drug Control Policy plan for implementation of Section 5301 through use of information generated by DOJ. The FCC will only use the automated records obtained from DOJ to make an initial determination of whether an individual applicant is subject to a denial of all Federal benefits or FCC benefits imposed under Section 5301 of the *Anti-Drug Abuse Act of 1988.*

purposes of locating individuals to establish paternity, establishing and modifying orders of child support, identifying sources of income, and for other child support enforcement actions as required by the *Personal Responsibility and Work Opportunity Reconciliation Act.*

6. Financial Obligations under the Debt Collection Acts—To other Federal agencies for the purpose of collecting and reporting on delinquent debts as authorized by the *Debt Collection Improvement Act of 1996.* A record from this system may be disclosed to any Federal, state, or local agency to conduct an authorized computer matching program in compliance with *the Privacy Act of 1974,* as amended, to identify and locate individuals who are delinquent in their repayment of certain debts owed to the U.S. Government. A record from this system may be used to prepare information on items included, but not limited to income assessments required for taxation or other purposes to be disclosed to Federal (*i.e.,* IRS), state, and local governments.

7. ''Do Not Pay'' System—To the Treasury Department, Bureau of Public Debt and its authorized contractors and representatives for compliance with collection laws and to prevent improper payment and for purposes of verifying payment eligibility using Treasury's ''Do Not Pay'' (DNP) system and effecting payments. Records may also be disclosed to Treasury pursuant to a DNP computer matching agreement between the FCC and Treasury for purposes authorized by 31 U.S.C. 3321, if the matching program requires data from this system of records. Additionally, records will be routinely disclosed to the Treasury and to other Federal agencies for the purpose of collecting and reporting on delinquent debts as authorized by the Debt Collection Improvement Act of 1996, as amended. Records may be disclosed to any Federal, state, or local agency to conduct an authorized computer matching program in compliance with *the Privacy Act of 1974,* as amended, to identify and locate individuals who are delinquent in their repayment of certain debts owed to the U.S. Government. Finally, records may be disclosed to the Treasury Department and its authorized representatives and the Department of Justice for purposes of reporting the results of debt collection or debt compromise to prepare necessary federal, state, or local income and tax reporting records and reports, *e.g.,* IRS Form 1099.

8. Financial Obligations as required by the National Finance Center (USDA), *et al.*—To the National Finance Center (the FCC's authorized payroll office), the Department of the Treasury Debt Management Services, and/or a current employer for financial obligations that include, but are not limited to those that effect a salary, IRS tax refund, tax or other debt liabilities of State, Municipality or other government agencies and entities, or administrative offsets necessary to satisfy an indebtedness; and to Federal agencies to identify and locate former employees for the purposes of collecting such indebtedness, including through administrative, salary, or tax refund offsets. Identifying and locating former employees, and the subsequent referral to such agencies for offset purposes, may be accomplished through authorized computer matching programs. Disclosures will be made only when all procedural steps established by the *Debt Collection Act of 1982* and the *Debt Collection Improvement Act of 1996* or the *Computer Matching and Privacy Protection Act of 1988,* as appropriate, have been taken.

9. Adjudication and Litigation—To the Department of Justice (DOJ), in a proceeding before a court, or other administrative or adjudicative body before which the FCC is authorized to appear, when: (a) The FCC or any component thereof; (b) any employee of the FCC in his or her official capacity; (c) any employee of the FCC in his or her individual capacity where DOJ or the FCC has agreed to represent the employee; or (d) the United States is a party to litigation or has an interest in such litigation, and the use of such records by DOJ or the FCC is deemed by the FCC to be relevant and necessary to the litigation.

11. Law Enforcement and Investigation—To disclose pertinent information to the appropriate Federal, State, or local agencies, authorities, and officials responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where the FCC becomes aware of an indication of a violation or potential violation of civil or criminal statute, law, regulation, or order.

12. Congressional Inquiries—To provide information to a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of that individual.

13. Government-wide Program Management and Oversight—To the National Archives and Records Administration (NARA) for use in its records management inspections; to the Government Accountability Office (GAO) for oversight purposes; to the Department of Justice (DOJ) to obtain that department's advice regarding disclosure obligations under the Freedom of Information Act (FOIA); or to the Office of Management and Budget (OMB) to obtain that office's advice regarding obligations under the Privacy Act.

14. Employment, Clearances, Licensing, Contract, Grant, or other Benefits Decisions by the Agency—To a Federal, State, local, foreign, tribal, or other public agency or authority maintaining civil, criminal, or other relevant enforcement records, or other pertinent records, or to another public authority or professional organization, if necessary to obtain information relevant to an investigation concerning the hiring or retention of an employee or other personnel action, the issuance or retention of a security clearance, the classifying of jobs, the letting of a contract, or the issuance or retention of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decisions on the matter.

15. Employment, Clearances, Licensing, Contract, Grant, or other Benefits Decisions by Other than the Agency—To a Federal, State, local, foreign, tribal, or other public agency or authority of the fact that this system of records contains information relevant to the hiring or retention of an employee, the issuance or retention of a security clearance, the conducting of a suitability or security investigation of an individual, the classifying of jobs, the letting of a contract, or the issuance or retention of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the agency's decision on the matter. The other agency or licensing organization may then make a request supported by the written consent of the individual for the entire records if it so chooses. No disclosure will be made unless the information has been determined to be sufficiently reliable to support a referral to another office within the agency or to another Federal agency for criminal, civil, administrative, personnel, or regulatory action.

16. Labor Relations—To officials of labor organizations recognized under 5 U.S.C. Chapter 71 upon receipt of a formal request and in accord with the conditions of 5 U.S.C. 7114 when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working condition.

17. Federal Labor Relations Authority—To disclose information to the Federal Labor Relations Authority

when requested in connection with investigations of allegations of unfair labor practices or matters before the Federal Service Impasses Panel (FSIP).

18. Merit Systems Protection Board—To disclose information to officials of the Merit Systems Protection Board or the Office of the Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of the FCC rules and regulations, investigations of alleged or possible prohibited personnel practices, and such other functions, *e.g.,* as promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

19. Equal Employment Opportunity Commission (EEOC)—To disclose information to the EEOC when requested in connection with investigations into alleged or possible discrimination practices in the Federal sector, compliance by Federal agencies with the Uniform Guidelines on Employee Selection Procedures or other functions vested in the Commission and to otherwise ensure compliance with the provisions of 5 U.S.C. 7201.

20. Non-Federal Personnel—To disclose information to contractors performing or working on a contract for the Federal Government.

21. Statistical/Analytical Studies—To provide to Congress and the Office of Management and Budget with summary descriptive statistics and analytical studies in support of the financial and budgetary functions for which the records are collected and maintained, or for related FCC studies and reports. While published studies do not contain individual identifiers, in some instances the selection of elements of data included in the study may be structured in such a way as to make the data individually identifiable by inference.

22. Breach Notifications—To appropriate agencies, entities, and individuals, when: (1) The FCC suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the Commission has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Commission or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and individuals is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed compromise and to prevent, minimize, or remedy such harm.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Under 5 U.S.C. 552a(b)(12) of the Privacy Act, the Department of Treasury may disclose to a consumer reporting agency information regarding a claim by the Commission which is determined to be valid and overdue as follows: name, address, SSN or ITIN, and other information necessary to establish the identity of the individual or organization responsible for the claim:

1. The amount, status, and history of the claim; and

2. The program under which the claim arose.

The Commission may disclose the information specified in this paragraph under 5 U.S.C. 552a(b)(12) and the procedures contained in subsection 31 U.S.C. 3711(e). A consumer reporting agency to which these disclosures may be made is defined at 31 U.S.C. 3701(a)(3).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information in this system is maintained as follows:

1. Electronic data, records, and files are housed in the FCC's computer network databases and/or at a FCC authorized contractor;

2. The DOJ maintains the Drug Debarment data at its facilities and transfers the Drug Debarment data files to the FCC under the terms of the matching agreement. These files are immediately discarded by the FCC after being loaded into the secure database on the FCC's computer network; and

3. Paper documents, including printouts and other related materials, records, and files are stored in the FO office suite and at a FCC authorized contractors.

RETRIEVABILITY:

1. Retrieval of records in the FCC's financial and budgetary (electronic) information systems, subsystems, and databases includes, but is not limited to the individual's name and/or type of transaction, call sign, processing number, SSN, ITIN, FRN, vendor code, fee control number, payment ID number, and/or sequential number.

2. Paper documents, records, and files can be similarly retrieved (manually) by these data markers.

3. Retrieval of records in the Drug Debarment database is as follows:

(a) An initial search is done using the name and ITIN or name and zip code between the Drug Debarment database and the CORES registration databases (*i.e.,* from the database with the name of an application on file with the FCC, which the FCC will then review).

(b) A subsequent search is done if an individual with a preliminary match file an FCC application or requests services from the FCC. The FCC may obtain additional data elements from DOJ, such as address, zip code, and, if required by the FCC application, date of birth, in order to determine if there is an actual match.

(c) An additional file search, as required, may also include the FCC confirmation report, identifying information obtained from the DOJ debarment entry and any correspondence with the applicant attached to the individual's application.

SAFEGUARDS:

1. The FCC's IT privacy safeguards include a comprehensive and dynamic set of safety and security protocols that are designed to meet all Federal IT privacy standards, including those required by the National Institute of Standard and Technology (NIST) and the Federal Information Security Act of 2002 (FISMA). The protocols cover all electronic records, files, and data, including those that are housed in the FCC's computer network databases; and those information system databases that are housed at the FCC's authorized contractor(s). The DOJ's Drug Debarment Databases, which are co-located with and secured under these same safety and security standards as individual registration records, also comply with NIST and FISMA requirements. The drug debarment data files are immediately discarded by the FCC after being loaded into the secure database. In addition, the FCC discards extraneous information, unless it is required by the FCC to determine a data match, or for other requirements.

2. There are a limited number of paper documents, files, and records, which are stored in file cabinets in the FO office. All access points for the FO office suite are monitored. These cabinets are locked when not in use and/or at the end of the business day.

3. Furthermore, as part of the FCC's privacy safeguards, only authorized FCC supervisors, employees, and contractors (including sole proprietor contractors) may have access to the electronic data and the paper document files.

RETENTION AND DISPOSAL:

1. The financial records are retained at the FCC for six to seven years following the end of the current fiscal year:

(a) Financial records are stored at the FCC's facility for two years; then

(b) Financial records are transferred for to an authorized FCC contractor for off-site storage for the duration of the required records retention schedule period, *i.e.,* four years and three months.

2. The records are then transferred to the National Archives and Records Administration's (NARA) Federal Records Center and destroyed by shredding when 6 years and 3 months old. Electronic records are destroyed physically (electronic storage media) or by electronic erasure. Paper records are destroyed by shredding.

3. (a) The match reports from the Drug Debarment database list are retained by the FCC for only as long as it is necessary to obtain the debarment entry information and corresponding application for manual confirmation of the match. Thereafter, the paper match reports are shredded. The electronic data are destroyed by electronic erasure.

(b) However, periodically, a match report will be randomly retained for a period of an additional 90 to 120 days to provide a quality check of the verification process. Where the verification process establishes that a match does not indicate that the applicant has been denied Federal benefits under section 5301, the debarment entry information used in that determination is retained by the FCC for 30 days after the application has cleared the debarment check.

(c) The debarment entry information relating to match reports that is retained for quality control purposes is retained until that quality check is completed. Where a match is confirmed by the manual verification process, the debarment entry information is retained for a period of at least 90 days after the date of the letter referred to above. If the application contests the determination that a section 5301 denial of Federal benefits bars a grant of the application, the debarment entry information is retained until such time as the FCC's action on the application is no longer subject to review in any court.

SYSTEM MANAGER(S) AND ADDRESS:

Financial Operations (FO), Office of Managing Director (OMD), Federal Communications Commission (FCC), 445 12th Street SW., Room 1–A663, Washington, DC 20554.

NOTIFICATION PROCEDURE:

Privacy Manager, Information Technology (IT), Federal Communications Commission (FCC), 445 12th Street SW., Washington, DC 20554, or *Leslie.Smith@fcc.gov.*

Individuals must furnish reasonable identification by showing any two of the following: Social security card; driver's license; employee identification card; Medicare card; birth certificate; bank credit card; or other positive means of identification, or by signing an identity statement stipulating that knowingly or willfully seeking or obtaining access to records about another person under false pretenses is punishable by a fine of up to $5,000.

Individuals requesting access must also comply with the FCC's Privacy Act regulations regarding verification of identity and access to records (5 CFR part 0, subpart E).

RECORD ACCESS PROCEDURES:

Individuals wishing to request an amendment of records about them should follow the Notification Procedure above.

CONTESTING RECORD PROCEDURE:

Individuals wishing to contest information pertaining to him or her in the system of records should follow the Notification Procedure above.

RECORD SOURCE CATEGORIES:

The sources for the information include, but are not limited to, FCC employees (including interns), contract employees, and individuals who register to do business with the FCC, and the information obtained from the Federal Drug Debarment List database(s). This information is used to administer, manage, oversee, and perform the FCC's financial and budgetary operations, programs, services, and transactions, and related telecommunications activities as required by Federal statutes and regulations.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–24068 Filed 10–5–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Deletion of Items From Sunshine Act Meeting

September 29, 2016.

The following consent agenda has been deleted from the list of items scheduled for consideration at the Thursday, September 29, 2016, Open Meeting and previously listed in the Commission's Notice of September 22, 2016. The item remains on circulation and the sunshine period prohibition in 47 CFR 1.1203 will remain in effect until further notice.

4	MEDIA	*TITLE:* Expanding Consumers' Video Navigation Choices (MB Docket No. 16–42); Commercial Availability of Navigation Devices (CS Docket No. 97–80). *SUMMARY:* The Commission will consider a Report and Order that modernizes the Commission's rules to allow consumers to use a device of their choosing to access multichannel video programming instead of leasing devices from their cable or satellite providers.

* * * * *

Consent Agenda

The following Consent Agenda items have been deleted from the list of items scheduled for consideration at the Thursday, September 29, 2016, Open Meeting and previously listed in the Commission's Notice of September 22, 2016. Items 6 and 7 have been adopted by the Commission.

1	ENFORCEMENT	*TITLE:* Enforcement Bureau Action. *SUMMARY:* The Commission will consider an enforcement action.
2	ENFORCEMENT	*TITLE:* Enforcement Bureau Action. *SUMMARY:* The Commission will consider an enforcement action.
3	ENFORCEMENT	*TITLE:* Enforcement Bureau Action. *SUMMARY:* The Commission will consider an enforcement action.
4	ENFORCEMENT	*TITLE:* Enforcement Bureau Action. *SUMMARY:* The Commission will consider an enforcement action.

6	MEDIA	*TITLE:* Powell Meredith Communications Company, Application for Modification to Low Power Television Station KBFY–LP, Fortuna, Arizona. *SUMMARY:* The Commission will consider a Memorandum Opinion and Order concerning the Application for Review filed by PMCC.
7	MEDIA	*TITLE:* Bernard Dallas LLC, Assignor, and ACM Dallas V LLC, Assignee, Applications for Assignment of Licenses for KFCD(AM), Farmersville, Texas, and KHSE(AM), Wylie, Texas, and ACM Dallas V LLC, Assignor, and Hammond Broadcasting, LLC, Assignee, Application for Assignment of License for KHSE(AM), Wylie, Texas. *SUMMARY:* The Commission will consider a Memorandum Opinion and Order concerning an Application for Review of the Media Bureau's grant of license assignment applications.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–24276 Filed 10–4–16; 11:15 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination; 10006 First Integrity Bank, National Association, Staples, Minnesota

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10006 First Integrity Bank, National Association, Staples, Minnesota (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of First Integrity Bank, National Association (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective October 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: October 3, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–24179 Filed 10–5–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination, 10386 Bank of Shorewood, Shorewood, Illinois

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10386 Bank of Shorewood, Shorewood, Illinois (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of Bank of Shorewood (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective October 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: October 3, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–24217 Filed 10–5–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10065—Cooperative Bank; Wilmington, NC

NOTICE IS HEREBY GIVEN that the Federal Deposit Insurance Corporation (''FDIC'') as Receiver for Cooperative Bank, Wilmington, NC (''the Receiver'') intends to terminate its receivership for said institution. The FDIC was appointed receiver of Cooperative Bank on June 19, 2009. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: October 3, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–24178 Filed 10–5–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination; 10477, Parkway Bank, Lenoir, North Carolina

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10477, Parkway Bank, Lenoir, North Carolina (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of Parkway Bank (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective October 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: October 3, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–24181 Filed 10–5–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to all Interested Parties of the Termination of the Receivership of 10206—Key West Bank, Key West, Florida

Notice is hereby given that the Federal Deposit Insurance Corporation (''FDIC'') as Receiver for Key West Bank, Key West, Florida (''the Receiver'') intends to terminate its receivership for said institution. The FDIC was appointed receiver of Key West Bank on March 26, 2010. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: October 3, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–24180 Filed 10–5–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination, 10118 Brickwell Community Bank, Woodbury, Minnesota

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10118 Brickwell Community Bank, Woodbury, Minnesota (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of Brickwell Community Bank (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective October 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: October 3, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–24218 Filed 10–5–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 31, 2016.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528. Comments can also be sent electronically to or *Comments.applications@rich.frb.org:*

1. *HomeTrust Bancshares, Inc.,* Asheville, North Carolina; to acquire 100 percent of the voting securities of TriSummit Bancorp, Inc., Kingsport, Tennessee, and thereby indirectly acquire TriSummit Bank, Kingsport, Tennessee.

Board of Governors of the Federal Reserve System, October 3, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–24222 Filed 10–5–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank

indicated or the offices of the Board of Governors not later than October 31, 2016.

A. Federal Reserve Bank of Boston (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210–2204. Comments can also be sent electronically to *BOS.SRC.Applications.Comments@bos.frb.org:*

1. *TCT Holdings Inc., Teachers Insurance and Annuity Association of America and TIAA Board of Overseers,* all of New York, New York; to acquire EverBank Financial Corp and thereby indirectly acquire EverBank, both of Jacksonville, Florida.

Board of Governors of the Federal Reserve System, October 3, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–24221 Filed 10–5–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–0733]; [Docket No. CDC–2016–0095]

Proposed Data Collections Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as requires by the Paperwork Reduction Act of 1995. This notice invites comments on Early Hearing Detection and Intervention (EDHI) Hearing and Screening Follow-up Survey.

DATES: Written comments must be received on or before December 5, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0095 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instruction for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulation.gov*, including any personal information provided. For access to the docket to read the background documents or comments received, go to *Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, and each reinstatement of previously approved information collection before submitting the collect to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Early Hearing Detection and Intervention (EDHI) Hearing and Screening Follow-up Survey (OMB No. 0920–0733, Expiration 08/30/2016)—Reinstatement with Change—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Human Development and Disability, located within NCBDDD, promotes the health of babies, children, and adults, with a focus on preventing birth defects and developmental disabilities and optimizing the health outcomes of those with disabilities. As part of these efforts the Center is actively involved in addressing the early identification of hearing loss among newborns and infants. Congenital hearing loss is a common birth defect that affects 1 to 3 per 1,000 live births, or approximately 12,000 children across the United States annually.[1 2] Studies have shown that children with a delayed diagnosis of hearing loss can experience preventable delays in speech, language, and cognitive development.[3–5] To ensure children with hearing loss are identified as soon as possible, many states and United States (U.S.) territories have implemented Early Hearing Detection and Intervention (EHDI) programs and enacted laws related to infant hearing screening. The majority of these EHDI programs have adopted the ''1–3–6'' plan, which consists of three core goals: (1) Screening all infants for hearing loss before 1 month of age, (2) ensuring diagnostic audiologic evaluation before 3 months of age for those who do not pass the screening, and (3) enrollment in early intervention services before 6 months of age for those identified with hearing loss.

Federal support for identifying children with hearing loss began with the Children's Health Act of 2000, which authorized federal programs to support EHDI activities at the state level. Since then, funds have been distributed to states via cooperative agreements from the CDC and grants from the Health Resources and Services Administration (HRSA). States are using these federal monies to enhance EHDI programs and develop corresponding tracking and surveillance systems. These systems are intended to help EHDI programs ensure infants and children are receiving recommended

hearing screening, follow-up, and intervention services.

The CDC's NCBDDD will fund this work to obtain standardized annual jurisdictional data related to the number of children screened for hearing loss, referred for and receiving follow-up testing (*e.g.,* diagnostic audiologic evaluation). As with the original and reinstated information collection the overall purpose of this updated survey is to consistently gather the aggregate-level data required to assess progress toward the National EHDI Goals.

Proposed changes for the updated survey have been made in response to feedback from respondents and requests for additional information from state and national partners. These updates are intended to further increase the standardization and completeness of the data collected and make the survey easier to complete. These changes include adding new fields to capture data about hearing screening conducted by using one-stage, two-stage, or blended (both one-stage and two-stage) screening protocol. In addition, fields were added to be able to report the number of occurring homebirths and the number of infants not documented to have received recommended screening, diagnostic and/or intervention services, due to reasons such as the infant being adopted, no referral from the Primary Care Physician (PCP)/Ear-Nose-Throat (ENT) specialist and/or due to medical reasons. Several fields have been removed in order to improve data quality and better evaluate whether jurisdictions are meeting the nationwide benchmarks. The table for reporting type and severity of hearing loss data has been updated so that this data can be reported using only the classification system from the American Speech and Hearing Association (ASHA). The table for reporting demographics has also been updated to include fewer columns, in order to improve data quality and data standardization with the previous sections of the survey.

The collected data will continue to be used in four key ways. First, it will be used to determine annual rates of hearing screening, referral for further diagnostic testing, loss to follow-up, incidence of hearing loss in infants, and enrollment in early intervention. These data will assist in determining if infants and children are receiving recommended EHDI-related services in a timely fashion. The information is intended to be made available through presentations, articles related to EHDI programs and infant hearing loss, and online at: *www.cdc.gov/ncbddd/hearingloss/ehdi-data.html.*

Second, the data will be used to determine rates of loss to follow-up within different stages of the EHDI process. Aggregated information about maternal race, ethnicity, education, and age will be used to help determine whether rates of loss to follow-up are correlated with any of these demographic variables. As with the most recent reinstatement with change (2013), the updated survey will continue to use same set of demographic data items, which will make it possible to continue analyzing the association between factors such as maternal race and loss to follow-up, maintain comparability between previous and future data, and minimize burden on respondents by continuing to request the same data that programs are currently collecting and able to report. This information is anticipated to continue to be important in developing methods to help minimize loss to follow-up so all children receive recommended hearing-related services in a timely manner.

Third, the data will be helpful in determining to what extent jurisdictional tracking and surveillance systems are capturing essential information related to follow-up services, identification, and enrollment in early intervention. It will also be used by CDC EHDI to identify areas in jurisdictional EHDI systems that may require additional modification. This is anticipated to be helpful in providing technical support to funded jurisdictions as well as for assessing the impact of federal initiatives related to hearing loss in infants and children.

Fourth, the requested data will aid in efforts to determine the prevalence of differing degrees of hearing loss (*e.g.,* mild, severe, profound, etc.) among infants and children.

Information provided by this updated survey also has the potential to be used for other purposes. These include quality improvement activities by jurisdictional EHDI programs (*e.g.,* identifying areas within the EHDI processes that could benefit from further development) and providing requested data for Healthy People 2020, Objective ENT–VSL–1 on newborn hearing screening, evaluation, and intervention. In addition, the aggregate-level data will continue to be made available online to other state and federal agencies, organizations, and the general public.

The total burden hours is 238.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
EHDI Program State Program Coordinators Contacted	Survey Directions	59	1	10/60	10
EHDI Program State Program Coordinators who return the survey	Survey	57	1	240/60	228
Totals					238

Leroy A. Richardson

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–24132 Filed 10–5–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2896]

Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss scientific and technical issues relating to formulation development and pre-market evaluation of opioid drug products with abuse-deterrent properties. The meeting is intended to give FDA the opportunity to discuss, and seek public input from stakeholders on, the approach to testing FDA recommended in its draft guidance ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products.'' The meeting will also provide an opportunity to discuss FDA's efforts to develop standardized in vitro testing methodologies for evaluating the abuse deterrence of opioid drug products. FDA is seeking input from all stakeholders, including patients, health care providers, health care payers, the pharmaceutical industry, patient advocates, academics, researchers, and other government entities.

FDA may hold one or more additional meetings in the future to discuss the risk-benefit paradigm for opioid drug products to ensure that FDA is appropriately considering the full public health impact of prescription opioid drug products and the post-market impact (''real world effects'') of abuse-deterrent opioid drug products.

DATES: The public meeting will be held on October 31, 2016, from 8:30 a.m. to 4:30 p.m. and November 1, 2016, from 8:30 a.m. to 4 p.m. The meeting may be extended or end early depending on the level of public participation. Individuals seeking to attend or to present at the meeting must register by October 17, 2016. Please register here for the meeting: *http://www.cvent.com/d/wvq0sm/4W.* Electronic or written comments regarding scientific and technical issues relating to formulation development and pre-market evaluation of abuse-deterrent properties of opioid drug products will be accepted until December 1, 2016.

ADDRESSES: The public meeting will be held at College Park Marriott Hotel and Conference Center, 3501 University Blvd. East, Hyattsville, MD 20783.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2896 for ''Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 3 days before the public meeting at: *http://www.fda.gov/Drugs/NewsEvents/ucm509853.htm.* FDA will also post a link to the live Webcast of this public meeting on the day of the public meeting.

FOR FURTHER INFORMATION CONTACT: Michelle Eby, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6184, Silver Spring, MD 20993, 301–796–4714, *Michelle.Eby@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Prescription opioid analgesics are an important component of modern pain management. Prescription opioid analgesic products such as oxycodone, hydrocodone, and morphine, are widely prescribed for the treatment of pain, and certain opioid drug products are also used in opioid dependence treatment programs. When used properly, opioid drug products can provide significant benefits for patients. Unfortunately, misuse and abuse of opioid drug products is a serious public health problem.

When misused or abused, opioid drug products can cause serious harm, including addiction, overdose, and death. According to the Centers for Disease Control and Prevention (CDC), prescription opioid drug products were involved in over 14,000 deaths in 2014.[1] FDA is determined to help defeat this epidemic through an adaptive, science-based approach.

In February 2016, FDA announced a comprehensive action plan to take concrete steps toward reducing the impact of opioid abuse on families and communities.[2] As part of this plan, FDA strongly supports the development of, and transition to use of, opioid drug products with meaningful abuse-deterrent formulations. FDA has taken and is continuing to take steps to incentivize and support the development of opioid drug products with progressively better abuse-deterrent properties. These steps include working with individual sponsors on promising abuse-deterrent technologies, publishing guidance on the evaluation and labeling of abuse-deterrent drug products, and conducting and supporting research in developing appropriate pre-market testing methodologies for evaluating the abuse deterrence of both innovator and generic drugs.

FDA believes abuse-deterrent technologies can and will improve substantially and can make a real impact in the fight against prescription opioid abuse. FDA hopes that as the market transitions to abuse-deterrent formulations, abuse rates will decrease and the most significant consequences of that abuse (addiction, overdose, and death) will diminish. To that end, fostering the development, marketing, and iterative improvement of abuse-deterrent formulations of opioid drug products, including generic opioid drug products, is a top priority. It is important that generic versions of opioids that reference approved opioids whose labeling describes abuse-deterrent properties are available to help ensure widespread access to safe and effective analgesics for patients who need them and to accelerate the prescribing of abuse-deterrent opioids. Such generic opioids should be no less abuse-deterrent than the opioids they reference; otherwise opioid abusers could preferentially seek out and abuse easier-to-abuse generics.

FDA's work to date to support the development, marketing, and iterative improvement of abuse-deterrent formulations includes:

- Holding a public meeting in October 2014 to discuss the ''Development and Regulation of Abuse-Deterrent Formulations of Opioid Medications;''
- Issuing a final guidance in April 2015 on the ''Abuse-Deterrent Opioids—Evaluation and Labeling.'' This guidance explains FDA's current thinking about the studies, both pre- and post-marketing, that should be conducted to demonstrate that a given formulation for which a new drug application (NDA) is submitted has abuse-deterrent properties. It also makes recommendations about how those studies should be performed and evaluated and what information about a product's abuse-deterrent properties should be included in labeling;
- To date, approving seven opioid analgesic drug products with labeling describing abuse-deterrent properties[3] consistent with the final guidance on evaluation and labeling of abuse-deterrent opioids;
- Seeking guidance from outside experts in the fields of pain management and drug abuse. For example, FDA has asked the National Academies of Sciences, Engineering, and Medicine to help develop a framework for opioid drug product review, approval, and monitoring that balances individual needs for pain control with the risk of addiction, as well as the broader public health consequences of opioid drug product misuse and abuse;
- Conducting or supporting research on opioid drug product formulations designed to deter abuse. This includes development of in vitro testing methodologies to assess purportedly abuse-deterrent formulations; and
- Issuing a draft guidance on the ''General Principles for Evaluating Abuse Deterrence of Generic Solid Oral Opioid Drug Products.''

In the notice of availability for the draft guidance on evaluating abuse deterrence of generic opioid drug products, FDA announced its intent to hold a public meeting following the close of the comment period to discuss further the pre-market evaluation of the abuse deterrence of generic opioid drug products and related issues, as appropriate. FDA is opening a docket and holding this public meeting to further discuss pre-market evaluation of the abuse deterrence of generic opioid drug products and the development of standardized in vitro testing methodologies for evaluating the abuse deterrence of opioid drug products.

Day 1 of this meeting will focus on scientific and technical issues related to the pre-market evaluation of the abuse deterrence of generic opioid drug products. It is important to have a viable pathway for approval of generic abuse-deterrent opioid drug products to further FDA's goal to transition to abuse-deterrent formulations as FDA looks forward to a future in which all or substantially all opioid medications are less susceptible to abuse than the formulations on the market today. The availability of generic versions of opioid drug products that reference listed drugs whose labeling describes abuse-deterrent properties can help to ensure access to safe and effective, and affordable, opioid analgesics for patients who need them.

Day 2 will focus on FDA's efforts to develop standardized in vitro testing methodologies for evaluating the abuse deterrence of opioid drug products. In vitro testing should, to the greatest extent possible, provide information sufficient to fully characterize a drug product's abuse-deterrent properties, including the degree of effort required to bypass or defeat those properties. In vitro studies should assess each potential route of abuse (including ingestion, injection, insufflation, and smoking) starting with simple and gentle mechanical and chemical manipulations progressing to complex and more destructive manipulations until a drug product's abuse-deterrent properties are defeated or compromised. To be sufficiently comprehensive, in vitro testing should address both the mechanisms by which abusers can be expected to attempt to deliberately overcome the abuse-deterrent properties of the product as well as the ways that patients may alter the formulation (intentionally or unintentionally) that

[1] Wide-Ranging Online Data for Epidemiologic Research (WONDER), National Center for Health Statistics; available at *http://wonder.cdc.gov.*

[2] *http://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm.*

[3] A list of opioid medications with FDA-approved labeling describing abuse-deterrent properties can be found at *http://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm514939.htm.*

change the rate or amount of drug released.

A. Day 1: FDA's Evaluation of Generic Abuse-Deterrent Opioids

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) (FD&C Act) permits any person to submit to the FDA an abbreviated new drug application (ANDA) to seek approval to market a generic version of a previously approved drug product. To obtain approval, an ANDA applicant is not required to provide independent evidence of the safety and effectiveness of the proposed generic drug. Instead, the applicant relies on FDA's finding that a previously approved drug product, i.e, the reference listed drug (RLD), is safe and effective, and must demonstrate, among other things, that the proposed generic drug is the ''same'' as the RLD in certain ways and is bioequivalent.

For FDA to approve an ANDA, the Agency must find, among other things, that the generic drug product has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and, with limited exceptions, labeling as the RLD, is bioequivalent to its RLD, that the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are adequate to assure and preserve its identity, strength, quality, and purity, and that the inactive ingredients and composition of the generic drug are not unsafe under the conditions of use prescribed, recommended, or suggested in the labeling. See section 505(j)(2)(A) and (j)(4) of the FD&C Act.

FDA classifies as ''therapeutically equivalent'' those products that meet the following general criteria: (1) They are approved as safe and effective; (2) they are pharmaceutical equivalents in that they contain identical amounts of the same active ingredient(s) with the same route of administration and dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent; (4) they are adequately labeled; and (5) they are manufactured in compliance with current good manufacturing practices regulations. See FDA's ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book), Preface. FDA believes that a product classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the reference product.

If the RLD's labeling describes properties that are expected to deter misuse or abuse then the potential ANDA applicant should evaluate its proposed generic drug product in comparative in vitro studies and, in some cases, in relevant pharmacokinetic or other studies to show that it is no less abuse-deterrent than the RLD with respect to all potential routes of abuse.[4]

It is important that generic versions of opioid drug products referencing opioid drug products with FDA-approved labeling describing abuse-deterrent properties are available to help ensure availability of analgesics for patients who need them. FDA is interested in supporting the submission of ANDAs for which the RLD is an opioid drug product whose labeling describes abuse-deterrent properties and ensuring that generic opioid drug products are no less abuse-deterrent than the RLD in its efforts to combat the opioid epidemic.

Topics for discussion during the open public comment period on Day 1 and by the panel:

- Based on any testing you have attempted to perform or performed in accordance with the March 2016 draft guidance, are there any aspects of the guidance that need clarification or improvement?
- Are there any characteristics of the currently approved abuse-deterrent RLDs for which issuance of product specific guidance, beyond what is described in FDA's March 2016 draft guidance, would facilitate development of abuse-deterrent generic opioid drug products?
- Are there approaches or technologies for evaluating the abuse deterrence of generic opioid drug products that were not included in the March 2016 draft guidance that should be?
- What additional actions could FDA take to encourage the submission of ANDAs that reference an opioid drug product whose labeling describes abuse-deterrent properties?
- Are there potential consequences of the development and introduction of abuse-deterrent opioid drug products that warrant further consideration?

B. Day 2: Development of Standardized In Vitro Testing To Evaluate Abuse Deterrence

The Office of Pharmaceutical Quality (OPQ) will discuss its vision for standardizing in vitro testing methodologies for evaluating purportedly abuse-deterrent formulations of opioid drug products. OPQ will also discuss the efforts being made to standardize in vitro testing conditions to apply to future products and some of the challenges being encountered. OPQ's Office of Testing and Research will then provide an update on its testing of abuse-deterrent formulations, including approaches being taken to simulate the ways individuals who abuse opioids manipulate opioid drug products for purposes of abuse (*e.g.,* crushing, heating, dissolving). FDA recognizes that new technologies for deterring abuse of oral opioid drug products are rapidly evolving and is seeking public input on novel mechanisms and approaches being considered so that it may further consider how testing could be standardized.

FDA intends to issue a general guidance describing FDA's recommendations for standardized in vitro testing to evaluate purported abuse-deterrent properties and considerations for a potential applicant as it develops an abuse-deterrent formulation of an opioid drug product. Building on the testing FDA has conducted and other available information including public input, FDA may recommend common protocols that incorporate standard test conditions, specified performance standards, control formulations and provide a tiered approach for determining when abuse-deterrent properties have been defeated and how that information may be used during drug development and for other relevant comparative situations. The guidance also may describe lifecycle considerations (*e.g.,* the need for testing abuse deterrence throughout shelf life to determine if any product changes over time affect abuse-deterrence performance) and provide additional guidance on evaluating novel technological approaches used to deter abuse of oral opioid drug products.

Topics for discussion during the open public comment period on Day 2 and by the panel:

- What technical and quantitative issues should FDA consider as it develops guidance to recommend standardization of in vitro testing to evaluate the abuse deterrence of opioid drug product formulations for various routes of abuse, including ingestion, insufflation, injection, and smoking? For example, what should FDA consider with respect to mechanical manipulations (*e.g.,* equipment, amount of effort, and time), chemical manipulations (*e.g.,* solvent choice and availability), particle size distribution,

[4] FDA's current thinking regarding the labeling of opioids is described in FDA's guidance for industry on ''Abuse-Deterrent Opioids—Evaluation and Labeling'' (April 2015). Any data relating to abuse-deterrent properties would be included in the DRUG ABUSE AND DEPENDENCE section of product labeling, 9.2 Abuse.

and volume of solvent used for extraction?

• How can FDA standardize in vitro testing to help substantiate appropriate and consistent product manufacture that assures abuse deterrence at release and through a drug product's shelf life?

• How can performance attributes measured by in vitro testing be quantified and linked to their impact on abuse deterrence? For example, discuss what amount of time delay in defeating an abuse-deterrent property should be considered significant and the basis for the recommendation.

• How can FDA build flexibility into standardized testing so that it may be suitable for application to emerging technologies? Are there any specific emerging technologies that might require new types of testing?

II. Registration and Accommodations

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public meeting must register by close of business on October 17, 2016.

If you need special accommodations because of a disability, please contact La'Shaune Morant, 240–316–3206, email: *lashaune@tepgevents.com* no later than October 12, 2016.

To register for the public meeting, please visit *http://www.cvent.com/d/wvq0sm/4W* (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**) by October 17, 2016. Those without Internet access may register by contacting La'Shaune Morant, 240–316–3206. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. You will receive confirmation after you have registered and been accepted or you will be notified if you are on a waiting list. FDA may allow onsite registration if space is available. If registration reaches maximum capacity, FDA will post a notice closing registration at *http://www.fda.gov/Drugs/NewsEvents/ucm509853.htm.*

Streaming Webcast of the Public Meeting: The meeting will also be Webcast. Persons interested in viewing the Webcast must register online by October 17, 2016. Early registration is recommended because Webcast connections may be limited. Organizations are requested to register all participants, but to view using one connection per location. A link to the live Webcast will be available at *http://www.fda.gov/Drugs/NewsEvents/ucm509853.htm* on the day of the public meeting. A video record of the public meeting will be available at *http://www.fda.gov/Drugs/NewsEvents/ucm509853.htm* following the meeting. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Requests for Oral Presentations: If you wish to present at the public meeting, you must register and indicate which topic(s) you wish to address: approach to testing FDA recommended in its draft guidance ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products,'' new technologies for deterring abuse of oral opioid drug products, or standardization of in vitro testing methodologies for evaluating purportedly abuse-deterrent formulations of opioid drug products. This will help FDA organize the presentations. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of the registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 24, 2016. All requests to make oral presentations must be received by the close of registration, October 17, 2016. If you are selected, any presentation materials must be emailed to Michelle Eby (see **FOR FURTHER INFORMATION CONTACT**) no later than October 27, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

FDA is holding this public meeting to obtain information on scientific and technical issues relating to formulation development and pre-market evaluation of opioid drug products with abuse-deterrent properties. In order to permit the widest possible opportunity for public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. The deadline for submitting comments related to this public meeting is December 1, 2016.

Accommodations: Attendees are responsible for their own hotel accommodations. Attendees making reservations at the College Park Marriott Hotel and Conference Center, 3501 University Blvd. East, Hyattsville, MD 20783, are eligible for a reduced rate of $231/night, not including applicable taxes. To receive the reduced rate, please reference ''FDA Opioid Drug Meeting'' if you make your reservation by calling 1–800–676–6137, or book your reservation at *http://www.marriott.com/meeting-event-hotels/group-corporate-travel/groupCorp.mi?resLinkData=FDA%20Opioid%20Drug%20Meeting%5Ewasum%60FDGFDGA%60231.00%60USD%60false%602%6010/30/16%6011/1/16%6010/12/16&app=resvlink&stop_mobi=yes.*

If you need special accommodations because of a disability, please contact La'Shaune Morant, 240–316–3206, *lashaune@tepgevents.com* no later than October 12, 2016.

III. Transcript Request

Transcripts of the meeting will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20850, and on the Internet at *http://www.regulations.gov* approximately 30 days after the meeting. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.*

Dated: September 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24234 Filed 10–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4561]

Head Lice Infestation: Developing Drugs for Topical Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Head Lice Infestation: Developing Drugs for Topical Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of head lice infestation. This guidance addresses the Agency's current thinking regarding the overall development program and clinical trial designs of drugs to support approval of an indication for topical treatment of head lice infestation. The information

presented will help sponsors plan clinical trials, design clinical protocols, and conduct and appropriately monitor clinical trials. This guidance finalizes the draft guidance of the same name issued on December 15, 2015.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–4561 for ''Head Lice infestation: Developing Drugs for Topical Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Strother D. Dixon, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5168, Silver Spring, MD 20993–0002, 301–796–1015.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Head Lice Infestation: Developing Drugs for Topical Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of head lice infestation. This guidance addresses the Agency's current thinking regarding the overall development program and clinical trial designs of drugs to support approval of an indication for topical treatment of head lice infestation. The information presented will help sponsors plan clinical trials, design clinical protocols, and conduct and appropriately monitor clinical trials. This guidance finalizes the draft guidance of the same name issued on December 15, 2015 (80 FR 77636). No changes were made from the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on developing drugs for topical treatment of head lice infestation. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information for prescription drug product labeling in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24233 Filed 10–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0530]

Tropical Disease Priority Review Vouchers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Tropical Disease Priority Review Vouchers.'' There has been significant outside interest in FDA's interpretation of the priority review voucher section in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) added by the Food and Drug Administration Amendments Act (FDAAA). This section makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease product applications that meet the criteria specified by the FD&C Act. This guidance explains to internal and external stakeholders how FDA is implementing the provisions of this section. This guidance finalizes the draft guidance of the same name issued October 2008.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2008–D–0530 for Tropical Disease Priority Review Vouchers; Guidance for Industry; Availability. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6360, Silver Spring, MD 20993–0002, 301–796–1182; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Tropical Disease Priority Review Vouchers.'' Section 1102 of FDAAA added section 524 to the FD&C Act. Section 524 is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world. By enacting section 524, Congress intended to stimulate new drug development for drug products to treat certain tropical diseases by offering additional incentives for obtaining FDA

approval for pharmaceutical treatments for these diseases. Under section 524, a sponsor of a human drug application for a qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the FD&C Act or section 351 of the Public Health Service Act. The guidance also provides information on using the priority review vouchers and on transferring priority review vouchers to other sponsors.

This guidance finalizes the draft guidance of the same name issued October 2008 and includes the following substantive changes based on public comment.

- The procedure for FDA to add diseases to the list is described
- Clarification is provided for when a voucher can be used
- A statement was added to say that FDA may provide a preliminary nonbinding opinion, before approval, that an application appears to meet the criteria for voucher eligibility
- Clarification is provided regarding the eligibility of combination products to receive a voucher
- Clarification is provided regarding the timing of payment of the priority review user fee
- Clarification is provided regarding whether FDA can remove tropical diseases from the list

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on obtaining tropical disease priority review vouchers. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0822.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: September 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24232 Filed 10–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that a meeting is scheduled for the Council on Graduate Medical Education (COGME). This meeting will be open to the public. Information about COGME and the agenda for this meeting can be obtained by accessing the COGME Web site at *http://www.hrsa.gov/advisorycommittees/bhpradvisory/COGME.*

DATES: October 20, 2016, 10:00 a.m.–4:30 p.m. ET

ADDRESSES: This meeting will be held by webinar only. Information on connecting to the webinar can be found on the COGME Web site.

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding COGME should contact Dr. Kennita Carter, Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, in one of three ways: (1) Send a request to the following address: Dr. Kennita Carter, Designated Federal Official, Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, 15N–116, Rockville, Maryland 20857; (2) call 301–945–3505; or (3) send an email to *KCarter@hrsa.gov.*

SUPPLEMENTARY INFORMATION: COGME provides advice and recommendations to the Secretary of HHS and to Congress on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, foreign medical school graduates, the nature and financing of medical education training, and the development of performance measures and longitudinal evaluation of medical education programs.

During the meeting, COGME members will discuss topics and issues related to the preparation of its 23rd report. COGME's reports are submitted to the Secretary of HHS; the Committee on Health, Education, Labor, and Pensions of the Senate; and the Committee on Energy and Commerce of the House of Representatives.

Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to COGME should be made using the contact address or phone number above by October 13, 2016.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–24167 Filed 10–5–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP Web site at: *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.*

DATES: The meeting will be held on Tuesday, October 25, 2016, from 8:30 a.m. until 5:00 p.m. and Wednesday, October 26, 2016, from 8:30 a.m. until 4:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP or Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP); U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as

amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., on Tuesday, October 25, followed by opening remarks from Dr. Jerry Menikoff, Executive Secretary of SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair. The Subpart A Subcommittee (SAS) will then present their report, including recommendations regarding single IRB review and the draft joint OHRP–FDA draft guidance, ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' This will be followed by the Subcommittee on Harmonization's (SOH) report, including recommendations involving clustered randomized trials, benchmarking, and the ''NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,'' Appendix M.

SAS was established by SACHRP in October 2006. The subcommittee is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

SOH was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. On Wednesday, October 26, 2016, SACHRP will discuss recommendations from the SOH on the FDA Draft Guidance ''Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices,'' issued July 27, 2016.

The meeting will adjourn at 4:30 p.m. October 26, 2016. Time for public comment sessions will be allotted both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting. Registration is required for participation in the on-site public comment session; individuals may register on the day of the meeting. Individuals who would like to submit written statements as public comment should email or fax their comments to SACHRP at *SACHRP@hhs.gov* at least five business days prior to the meeting. Note that public comment must be relevant to agenda topics.

Dated: October 3, 2016.

Julia Gorey,

Executive Director, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2016–24251 Filed 10–5–16; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Solicitation of Written Comments on Modifications of Healthy People 2020 Objectives

AGENCY: Office of the Secretary, Office of the Assistant Secretary of Health, Office of Disease Prevention and Health Promotion, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services solicits written comments regarding a new objective proposed to be added to Healthy People 2020 since the fall 2015 public comment period. Public participation helps shape Healthy People 2020, its framework, objectives, organization, and targets. Healthy People provides opportunities for public input periodically throughout the decade to ensure that Healthy People 2020 reflects current public health priorities and public input. The updated set of Healthy People 2020 objectives will be incorporated on *www.HealthyPeople.gov.* This set will reflect further review and deliberation by the topic area workgroups, Federal Interagency Workgroup on Healthy People 2020, and other Healthy People 2020 stakeholders.

DATES: Written comments will be accepted until 5:00 p.m. ET on October 27, 2016.

ADDRESSES: Written comments will be accepted via an online public comment database at *http://www.healthypeople.gov/2020/about/history-development/Public-Comment;* by mail at the Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, Attn: Public Comment, 1101 Wootton Parkway, Room LL–100, Rockville, MD 20852; fax—(240) 453–8281; or email—*HP2020@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Caitie Blood, MPH, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Room LL–100, Rockville, MD 20852, *Caitlin.Blood@HHS.gov* (email), (240) 453–8265 (telephone), (240) 453–8281 (fax).

SUPPLEMENTARY INFORMATION: For three decades, Healthy People has provided a comprehensive set of national 10-year health promotion and disease prevention objectives aimed at improving the health of all Americans. Healthy People 2020 objectives provide a framework by presenting a comprehensive picture of the nation's health at the beginning of the decade, establishing national goals and targets to be achieved by the year 2020, and monitoring progress over time. The U.S. Department of Health and Human Services is soliciting the submission of written comments regarding a new objective proposed to be added to Healthy People 2020 since the fall 2015 public comment period.

Healthy People 2020 is the product of an extensive collaborative process that relies on input from a diverse array of individuals and organizations, both within and outside the federal government, with a common interest in improving the nation's health. Public comments were a cornerstone of Healthy People 2020's development. During the first phase of planning for Healthy People 2020, HHS asked for the public's comments on the vision, mission, and implementation of Healthy People 2020. Those comments helped set the framework for Healthy People 2020. The public was also invited to submit comments on proposed Healthy People 2020 objectives, which helped shape the final set of Healthy People 2020 objectives.

The public is now invited to comment on a new objective proposed to be added to Healthy People 2020, which can be found at *http://www.healthypeople.gov/2020/about/history-development/Public-Comment.* This new objective was developed by the HIV topic area workgroup led by the Centers for Disease Control and Prevention and Health Resources and Services Administration. It has been reviewed by the Federal Interagency Workgroup on Healthy People 2020 and is presented now for the public's review and comment. Comments are restricted to this specific HIV objective. Having reached the midpoint in the decade, Healthy People will not be soliciting proposals for additional new objectives.

Written comments will be accepted at *http://www.healthypeople.gov/2020/about/history-development/Public-Comment.* The public will also be able

to submit written comments via mail, fax, and email (see contact information above). Comments received in response to this notice will be reviewed and considered by the appropriate topic area workgroup, Federal Interagency Workgroup on Healthy People 2020, and other Healthy People 2020 stakeholders.

Dated: October 3, 2016.

Don Wright,

Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion).

[FR Doc. 2016–24250 Filed 10–5–16; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; P01 Review: Heroin Addiction.

Date: October 14, 2016.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005.

Contact Person: Jana Drgonova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, *jdrgonova@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 29, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24125 Filed 10–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review: Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Diseases and Pathophysiology of the Visual System Study Section.

Date: October 27–28, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC Convention Center, 900 10th Street NW., Washington, DC 20001.

Contact Person: Nataliya Gordiyenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301.435.1265, *gordiyenkon@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Mucosal Inflammation, Allergy and Asthma.

Date: October 28, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person:

Deborah Hodge, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4207 MSC 7812, Bethesda, MD 20892, (301) 435–1238, *hodged@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Conferences and Meetings: Office of Research Infrastructure Programs (ORIP).

Date: October 31, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Cathleen L. Cooper, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2130, MSC 7720, Bethesda, MD 20892, 301–443–4512, *cooperc@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Infectious Diseases, Reproductive Health, Asthma and Pulmonary Conditions, Study Section.

Date: November 2–3, 2016.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 257–2638, *steeleln@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Review of Neuroscience AREA Grant Applications.

Date: November 3–4, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue NW., Washington, DC 20036.

Contact Person: Richard D. Crosland, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, 301–435–1220, *crosland@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Drug Discovery and Mechanisms of Antimicrobial Resistance.

Date: November 3–4, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton McLean Tysons Corner, 7920 Jones Branch Drive, McLean, VA 22102.

Contact Person: Guangyong Ji, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–1146, *jig@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Clinical Neuroscience and Disease.

Date: November 3, 2016.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Bruce Reed, Ph.D., Director Division, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4160, MSC 7806, Bethesda, MD 20892, 301–594–9159, *reedbr@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Drug Discovery and Mechanisms of Antimicrobial Resistance.

Date: November 3, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton McLean Tysons Corner, 7920 Jones Branch Drive, McLean, VA 22102.

Contact Person: John C. Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, (301) 435–2398, *pughjohn@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 30, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24126 Filed 10–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Lasker Clinical Research Scholars Program (Si2/R00).

Date: November 1, 2016.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities/ Room 3G31B National Institutes of Health, NIAID, 5601 Fishers Lane MSC 9823, Rockville, MD 20892, (240) 669–5060, *james.snyder@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 30, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24129 Filed 10–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Consortium for Food Allergy Research: Clinical Research Units (UM1).

Date: November 16–18, 2016.

Time: 7:30 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Louis A. Rosenthal, Ph.D., Scientific Review Officer Scientific Review Program, Division of Extramural Activities, Rm 3G42B National Institutes of Health/ NIAID, 5601 Fishers Lane, MSC–79823 Bethesda, MD 20892–9823, (240) 669–5070, *rosenthalla@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 30, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24130 Filed 10–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. Technology description follows.

Use of Roseomonas species to treat eczematous (atopic dermatitis) skin disease Description of Technology:

Atopic dermatitis, also known as eczema, is a chronic itchy skin disease that affects over 20% of infants and young children in industrialized nations and may persist into adulthood for up to 50% of these cases, making it one of the most common skin diseases in the US and other developed countries.

Scientists at NIAID have developed a method of treating or preventing atopic dermatitis via the topical application of selected probiotic strains of gram-negative *Roseomonas mucosa* bacteria. This approach avoids the exhausting treatment demands of standard therapies and has been shown to be beneficial in a preclinical mouse model of atopic dermatitis.

Potential Commercial Applications:

- Treatment of eczema

Competitive Advantages:

- May be formulated as a cream or ointment

- Corticosteroid-free
- Animal data available

Development Stage:

- In vivo data available (animal)

Inventors: Ian A. Myles, Sandip Kumar Datta, all of NIAID.

Publications: Myles IA, et al. Transplantation of human skin microbiota in models of atopic dermatitis. JCI Insight, 2016, Jul 7; 1(10). [PMID 27478874].

Intellectual Property: HHS Reference No. E–099–2016/0—US Patent Application No. 62/324,762 filed April 19, Year 2016.

Licensing Contact: Dr. David Yang, 240–627–3413; *polung.yang@nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize the use of Roseomonas species to treat eczematous (atopic dermatitis) skin disease. For collaboration opportunities, please contact Dr. David Yang, 240–627–3413; *polung.yang@nih.gov.*

Dated: Septenber 30, 2016.

Suzanne Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2016–24134 Filed 10–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel Second Stage P01 Review.

Date: November 21, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, 7301 Waverly Street, Bethesda, MD 20817.

Contact Person: Ramesh Vemuri, Ph.D., Chief, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892, 301–402–7700, *rv23r@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 30, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24128 Filed 10–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the Board of Scientific Counselors for Basic Sciences, National Cancer Institute and the Board of Scientific Counselors for Clinical Sciences and Epidemiology, National Cancer Institute.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors for Basic Sciences, National Cancer Institute.

Date: November 14, 2016.

Time: 9:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 31 Center Drive, Building 31, C-Wing, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Contact Person: Mehrdad Tondravi, Ph.D., Chief, Institute Review Office, Office of the Director, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 3W302, Rockville, MD 20850, 240–276–5660, *tondravim@mail.nih.gov.*

Name of Committee: Board of Scientific Counselors for Basic Sciences, National Cancer Institute.

Date: November 14, 2016.

Time: 6:00 p.m. to 9:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hyatt Regency, 1 Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Mehrdad Tondravi, Ph.D., Chief, Institute Review Office, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 3W302, Rockville, MD 20850, 240–276–5660, *tondravim@mail.nih.gov.*

Name of Committee: Board of Scientific Counselors for Clinical Sciences and Epidemiology, National Cancer Institute.

Date: November 14, 2016.

Time: 6:00 p.m. to 9:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hyatt Regency, 1 Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Brian E. Wojcik, Ph.D., Executive Secretary, Institute Review Office, Office of the Director, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 3W414, Rockville, MD 20850, 240–276–5660, *wojcikb@mail.nih.gov.*

Name of Committee: Board of Scientific Counselors for Clinical Sciences and Epidemiology, National Cancer Institute.

Date: November 15, 2016.

Time: 8:30 a.m. to 2:45 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 31 Center Drive, Building 31, C-Wing, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Contact Person: Brian E. Wojcik, Ph.D., Executive Secretary, Institute Review Office, Office of the Director, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 3W414, Rockville, MD 20850, 240–276–5665, *wojcikb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 30, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24127 Filed 10–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Trauma and Burn P50 Research Centers.

Date: October 12, 2016.

Time: 12:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3AN18, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–3907, *pikbr@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 30, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24131 Filed 10–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group Myocardial Ischemia and Metabolism Study Section.

Date: October 27–28, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Downtown Silver Spring, 8506 Fenton St., Silver Spring, MD 20910.

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301–435–5575, *hamannkj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biobehavioral Regulation, Learning and Ethology.

Date: October 27, 2016.

Time: 4:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Unja Lucille Hayes, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1037, *unja.hayes@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel: Alzheimer's Disease Pilot Clinical Trials.

Date: October 31, 2016.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mark Lindner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7770, Bethesda, MD 20892, 301–915–6298, *mark.lindner@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel; Health Services Research on Minority Health and Health Disparities.

Date: November 1, 2016.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Valerie Durrant, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, (301) 827–6390, *durrantv@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR–15–358-Molecular and Cellular Causal Aspects of Alzheimer's Disease.

Date: November 2, 2016.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7850, Bethesda, MD 20892, 301–435–1203, *laurent.taupenot@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–15–358-Molecular and Cellular Causal Aspects of Alzheimer's Disease.

Date: November 2, 2016.

Time: 2:00 p.m. to 2:45 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Afia Sultana, Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1220, *sultanaa@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Synthetic and Biological Chemistry.

Date: November 3, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mike Radtke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892, 301–435–1728, *radtkem@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncological Sciences.

Date: November 3–4, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jian Cao, MD.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Vascular Biology and Pathobiology.

Date: November 3–4, 2016.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817, (Virtual Meeting).

Contact Person: Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, *zouai@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Bioengineering Sciences #3.

Date: November 3, 2016.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cell and Tissue Engineering and Analysis using Microfluidics, Bioprinting, and Bioreactors.

Date: November 4, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Capital View, 2850 South Potomac Avenue, Arlington, VA 22202.

Contact Person: Wenchi Liang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, 301–435–0681, *liangw3@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR: Development of Pediatric Formulations and Drug Delivery Systems.

Date: November 4, 2016.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Sharon S Low, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5104, MSC 5104, Bethesda, MD 20892–5104, 301–237–1487, *lowss@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846– 93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: September 29, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24124 Filed 10–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Development of a NANOG-Based Therapeutic for Cancer

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the U.S. Patents and Patent Applications listed in the Summary Information section of this notice to Inova Health System located in Falls Church, VA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before October 21, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Kevin W. Chang, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702 Telephone: (240) 276–6910; Facsimile: (240) 276–5504 Email: *changke@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. No. 61/420,214, filed December 6, 2010, entitled ''Allele Specific shRNAs For NANOG, Pharmaceutical Composition Comprising The shRNA, And Its Method of Use to Treat Cancer'' [HHS Reference No. E–294–2010/0–US–01]; International PCT Application No. PCT/US2011/063451, filed December 6, 2011, entitled ''Pharmaceutical Composition Comprising NANOG shRNA, and Method of Using NANOG shRNA to Treat Cancer'' [HHS Reference No. E–294–2010/0–PCT–02]; United States Patent No. 9,163,236, issued October 20, 2015, entitled ''Pharmaceutical Composition Comprising NANOG shRNA, and Method of Using NANOG shRNA to Treat Cancer'' [HHS Ref. No. E–294–2010/0–US–03]; and United States Patent Application No. 14/886,970 filed October 19, 2015, entitled, ''Pharmaceutical Composition Comprising NANOG shRNA, and Method of Using NANOG shRNA to Treat Cancer'' [HHS Ref. No. E–294–2010/0–US–04].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: ''Treatment or prevention of colorectal cancer in humans.''

The subject technologies are short hair-pin RNAs which inhibit NANOG or NANOGP8 for the treatment of cancer and viral vectors that encode the RNAs. The first generation of these vectors were non-replicating lentiviral based vectors that were introduced into cancer cells as a standard form of RNA inhibition, blocking the expression of NANOG or NANOGP8 protein. The most current version of the subject technology utilizes conditionally replicating, oncolytic adenovirus vectors. These adenovirus-based vectors grow in cells that express NANOGP8 but not in cells that lack NANOGP8 or where the shRNA has inhibited NANOGP8 expression. The vectors have been constructed to directly kill tumors and to inhibit the NANOGs to block cancer stem cell function in the tumors.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act,* 5 U.S.C. 552.

Dated: September 29, 2016.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–24133 Filed 10–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX17GG00995TR00]

Announcement of Scientific Earthquake Studies Advisory Committee Meeting

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of meeting.

SUMMARY: The Scientific Earthquake Studies Advisory Committee (SESAC) will hold its next meeting in the Mesa Room of the Golden Hotel at 800 11th Street, Golden, Colorado. The Committee is comprised of members from academia, industry, and State government. The Committee shall advise the Director of the U.S. Geological Survey (USGS) on matters relating to the USGS's participation in the National Earthquake Hazards Reduction Program. The Committee will receive reports on the status of activities of the Program and progress toward Program goals and objectives. The Committee will assess this information and provide guidance on the future undertakings and direction of the Earthquake Hazards Program. Focus topics for this meeting include a program review and strategic planning for 2016–2018.

DATES: The meeting will be held from 9:00 a.m. to 5:00 p.m. on November 7–8, 2016.

FOR FURTHER INFORMATION CONTACT: Dr. William Leith, U.S. Geological Survey, MS 905, 12201 Sunrise Valley Drive, Reston, Virginia 20192, (703) 648–6786, *wleith@usgs.gov*.

SUPPLEMENTARY INFORMATION: Meetings of the Scientific Earthquake Studies Advisory Committee are open to the public.

Authority: Public Law 106–503.

William Leith,

Senior Science Advisor for Earthquake and Geologic Hazards.

[FR Doc. 2016–24226 Filed 10–5–16; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[178A2100DD/AAKC001030/ A0A501010.999900 253G]

Renewal of Agency Information Collection for Grazing Permits

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of submission to OMB.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Indian Affairs (BIA) has submitted to the Office of Management and Budget (OMB) a request for renewal of the collection of information for Grazing Permits authorized by OMB Control Number 1076–0157. This information collection expires October 31, 2016.

DATES: Interested persons are invited to submit comments on or before November 7, 2016.

ADDRESSES: Please submit your comments to the Desk Officer for the Department of the Interior at the Office of Management and Budget, by facsimile to (202) 395–5806 or you may send an email to: *OIRA_Submission@omb.eop.gov.* Also please send a copy of your comments to David Edington, Office of Trust Services, 1849 C Street NW., Mail Stop 4637 MIB, Washington, DC 20240; facsimile: (202) 219–0006; email: *David.Edington@bia.gov.*

FOR FURTHER INFORMATION CONTACT: David Edington, Office of Trust Services, 1849 C Street NW., Mail Stop 4637 MIB, Washington, DC 20240; facsimile: (202) 219–0006; email: *David.Edington@bia.gov.* You may review the information collection request online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

I. Abstract

The ''American Indian Agricultural Resource Management Act,'' (AIARMA), 25 U.S.C. 3701 *et seq.,* authorizes the Secretary of the Interior, in participation with the beneficial owner of the land, to manage Indian agricultural lands in a manner consistent with identified Tribal goals and priorities for conservation, multiple use, sustained yield, and consistent with trust responsibilities, related to grazing on Tribal land, individually-owned Indian land, or government land. The regulations at 25 CFR 166, Grazing Permits, implement the AIARMA and include the specific information collection requirements.

This information collection allows BIA to obtain the information necessary to determine whether an applicant is eligible to acquire, modify, or assign a grazing permit on trust or restricted lands and to allow a successful applicant to meet bonding requirements. Some of this information is collected on forms. The burden hours for this continued collection of information are reflected in the Estimated Total Annual Hour Burden in this notice.

II. Request for Comments

The BIA requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) Ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) Ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor and an individual need not respond to, a collection of information unless it displays a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. Before including your address, phone number, email address or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

III. Data

OMB Control Number: 1076–0157.

Title: Grazing Permits, 25 CFR 166.

Brief Description of Collection: Submission of this information allows individuals or organizations to acquire or modify a grazing permit on Tribal land, individually-owned Indian land, or government land and to meet bonding requirements. Some of this information is collected on the following forms: Form 5–5423—Performance Bond, Form 5–5514—Bid for Grazing Privileges, 5–5515 Grazing Permit, Form 5–5516—Grazing Permit for Organized Tribes, Form 5–5517—

Free Grazing Permit, Form 5–5519—Cash Penal Bond, Form 5–5520—Power of Attorney, Form 5– 5521—Certificate and Application for On-and-Off Grazing Permit, Form 5522—Modification of Grazing Permit, Form 5– 5523—Assignment of Grazing Permit, Form 5–5524—Application for Allocation of Grazing Privileges, 5–5525 Authority to Grant Grazing Privileges on Allotted Lands, Form 5–5528—Livestock Crossing Permit, and Form 5–5529—Removable Range Improvement Records. Response is required to obtain or retain a benefit.

Type of Review: Revision of a currently approved collection.

Respondents: Tribes, Tribal organizations, individual Indians, and non-Indian individuals and associations.

Number of Respondents: 800.

Number of Responses: 7,810.

Frequency of Response: Annually.

Obligation to Respond: A response is required to obtain or maintain a benefit.

Estimated Time per Response: Varies from 20 minutes to one hour, with an average of less than one hour per response.

Estimated Total Annual Hour Burden: 2,701.

Estimated Total Annual Non-Hour Dollar Cost: $0.

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2016–24183 Filed 10–5–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM930000.L51010000.ER0000. LVRWG16G1190.16X; NMNM114507]

Notice of Intent To Prepare an Environmental Impact Statement and Resource Management Plan Amendment for the Verde Transmission Project in New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), the Federal Land Policy and Management Act of 1976, as amended, and the Bureau of Land Management's (BLM's) land use planning regulations, the BLM announces its intent to prepare an Environmental Impact Statement (EIS) evaluating the proposed 33-mile, 345-kilovolt (kV) Verde Transmission Project and potential amendment to the Taos Resource Management Plan (RMP) pursuant to the BLM's land use planning regulations. The BLM is the lead agency in the development of the EIS and will work in cooperation with the Bureau of Indian Affairs (BIA), the U.S. Army Corps of Engineers (USCOE), and the National Park Service (NPS). By this notice, the BLM is announcing the beginning of the scoping process to solicit public comments and identify issues on the proposed transmission line and a potential plan amendment.

DATES: Comments may be submitted in writing until December 5, 2016. The dates and locations of any scoping meetings will be announced at least 15 days in advance through local news media, newspapers, and the BLM Web site at: *http://www.blm.gov/nm/verde*. In order to be included in the analysis, all comments must be received prior to the close of the 60-day scoping period or 15 days after the last public meeting, whichever is later. Additional opportunities for public participation will be provided as appropriate.

ADDRESSES: You may submit comments or resource information by any of the following methods:

- *Web site: http://www.blm.gov/nm/verde*
- *Email: BLM_NM_Verde@blm.gov.*
- *Fax:* (505) 954–2136.
- *Mail:* Bureau of Land Management, New Mexico State Office, Verde Transmission Project, P.O. Box 27115, Santa Fe, NM 87502–0115.

Documents pertinent to the right-of-way (ROW) application for the proposed transmission line project may be examined at: Bureau of Land Management, New Mexico State Office, Public Room, 301 Dinosaur Trail, Santa Fe, NM 87508, and the BLM's Taos Field Office, 226 Cruz Alta Road, Taos, NM 87571–5983.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to the project mailing list, contact Adrian Garcia, BLM Project Manager, Verde Transmission Project, at the BLM New Mexico State Office, P.O. Box 27115, Santa Fe, NM 87502–0115, or by email at *BLM_NM_Verde@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1–800–877–8339 to contact the above individual during normal business hours. The Service is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Verde Transmission, LLC (Applicant) has submitted an application to the BLM for a right-of-way (ROW) to construct, operate, maintain, and eventually decommission a 345-kV overhead transmission line that would connect the existing Public Service Company of New Mexico (PNM) Ojo Substation in southern Rio Arriba County to the existing Norton Substation in Santa Fe County, New Mexico. The proposed line would cross approximately 10 miles of BLM land, 15 miles of tribal land, and 8 miles of private land. The permanent ROW requested for the project would be 150 feet wide if approved. Since the proposed transmission project would not be consistent with the existing visual resource management classifications of the area, as part of its review of the ROW application the BLM is also evaluating potential amendments to the visual resource classifications in the Taos Resource Management Plan.

The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives, and guide the planning process. Preliminary issues for analysis in the forthcoming EIS and the potential plan amendment have been identified by BLM personnel. The issues specific to the proposed transmission project include potential impacts to cultural, visual, and wildlife resources; the Old Spanish Trail National Historic Trail and the El Camino Real National Historical Trail; livestock grazing; opportunities for recreation; and socioeconomic impacts. Issues specific to the potential RMP amendment include a possible change to the visual resource management classification of the project area, as prescribed by the Taos RMP, which was originally designed to limit visual intrusions that create a contrast with the existing visual quality of the area.

If the ROW application or plan amendment is approved, the BLM would identify, analyze, and require mitigation, as appropriate, to address the reasonably foreseeable impacts to resources. Mitigation may include avoidance, minimization, rectification, reduction, or elimination over time, and compensatory mitigation. These potential measures may be considered at multiple scales, including the landscape-scale. You may submit comments on issues and planning criteria in writing to the BLM at any public scoping meeting, or you may submit them to the BLM using one of the methods listed in the **ADDRESSES** section above. To be most helpful, you must submit comments by the close of the 60-day scoping period or within 15 days after the last public meeting, whichever is later.

The BLM will utilize and coordinate the NEPA scoping process to help fulfill the public involvement process under the National Historic Preservation Act (54 U.S.C. 306108) as provided in 36 CFR 800.2(d)(3). The information about historic and cultural resources within the area potentially affected by the proposed action will assist the BLM in identifying and evaluating impacts to such resources.

The BLM will also consult with Indian tribes on a government-to-government basis in accordance with Executive Order 13175 and other policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. Federal, State, and local agencies, along with tribes and other stakeholders that may be interested in or affected by the proposed action, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the environmental analysis as a cooperating agency.

As part of the scoping process, the BLM will evaluate the issues to be addressed in the EIS and proposed plan amendment. Those issues will be placed into one of three categories:

1. Issues to be resolved in the EIS and plan amendment;
2. Issues to be resolved through policy or administrative action; or
3. Issues beyond the scope of this EIS and plan amendment.

The BLM will provide an explanation in the draft EIS/draft RMP amendment as to why an issue was placed in category two or three. The public is also encouraged to help identify any management questions and concerns that should be addressed in the EIS and plan amendment. The BLM will work collaboratively with interested parties to identify the management decisions that are best suited to local, regional, and national needs and concerns.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. The minutes and list of attendees for each scoping meeting will be available to the public and open for 30 days after the meeting to any participant who wishes to clarify the views he or she expressed.

The BLM will use an interdisciplinary approach to develop the EIS and RMP amendment in order to consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in the planning process: Cultural resources, outdoor recreation, rangeland management, realty, socioeconomics, visual resources, and biology.

Authority: Authority: 40 CFR 1501.7 and 43 CFR 1610.2

Amy Lueders,

State Director.

[FR Doc. 2016–24224 Filed 10–5–16; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO2200000.L10200000.PK0000. 00000000]

Renewal of Approved Information Collection; OMB Control No. 1004–0019

AGENCY: Bureau of Land Management, Interior.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Bureau of Land Management (BLM) has submitted an information collection request to the Office of Management and Budget (OMB) to continue the collection of information regarding the construction and maintenance of range improvement projects. The respondents include holders of BLM grazing permits or grazing leases; affected individuals and households; and affected tribal, state, and county agencies. The Office of Management and Budget (OMB) previously approved this information collection activity, and assigned it control number 1004–0019.

DATES: The OMB is required to respond to this information collection request within 60 days but may respond after 30 days. For maximum consideration, written comments should be received on or before November 7, 2016.

ADDRESSES: Please submit comments directly to the Desk Officer for the Department of the Interior (OMB #1004–0019), Office of Management and Budget, Office of Information and Regulatory Affairs, fax 202–395–5806, or by electronic mail at *OIRA_submission@omb.eop.gov.* Please provide a copy of your comments to the BLM. You may do so via mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: to Jean Sonneman at 202–245–0050.

Electronic mail: jesonnem@blm.gov.

Please indicate ''Attn: 1004–0019'' regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Kimberly Hackett, at 202–912–7216. Persons who use a telecommunication device for the deaf may call the Federal Information Relay Service at 1–800–877–8339, to leave a message for Ms. Hackett. You may also review the information collection request online at *http://www.reginfo.gov/public/.*

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act (44 U.S.C. 3501–3521) and OMB regulations at 5 CFR part 1320 provide that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond. In order to obtain and renew an OMB control number, Federal agencies are required to seek public comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d) and 1320.12(a)).

As required at 5 CFR 1320.8(d), the BLM published a 60-day notice in the **Federal Register** on March 30, 2016 (81 FR 17728), and the comment period ended May 31, 2016. The BLM received one comment. The comment was a general invective about the Federal government, the Department of the Interior, and the BLM. It did not address, and was not germane to, this information collection. Therefore, we have not changed the collection in response to the comment. The BLM now requests comments on the following subjects:

1. Whether the collection of information is necessary for the proper functioning of the BLM, including whether the information will have practical utility;
2. The accuracy of the BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;
3. The quality, utility and clarity of the information to be collected; and
4. How to minimize the information collection burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Please send comments as directed under **ADDRESSES** and **DATES**. Please

refer to OMB control number 1004–0019 in your correspondence. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The following information pertains to this request:

Title: Grazing Management: Range Improvements Agreements and Permits (43 CFR Subpart 4120).

OMB Control Number: 1004–0019.

Summary: This request pertains to range improvements on public lands managed by the BLM. Range improvements enhance or improve livestock grazing management, improve watershed conditions, enhance wildlife habitat, or serve similar purposes. At times, the BLM may require holders of grazing permits or gazing leases to install range improvements to meet the terms and conditions of their permits or leases. Operators may also come to the BLM with proposals for range improvements. Often the BLM, operators, and other interested parties work together and jointly contribute to construction of range improvements in order to facilitate improved grazing management or enhance other multiple uses. Cooperators may include lenders which provide the funds that operators contribute for improvements.

Frequency of Collection: On occasion.

Forms:

- Form 4120–6 (Cooperative Range Improvement Agreement); and
- Form 4120–7 (Range Improvement Permit).

Description of Respondents: Holders of BLM grazing permits or grazing leases; affected individuals and households; and affected tribal, state, and county agencies.

Estimated Annual Responses: 1,110.

Estimated Annual Burden Hours: 1,640.

Estimated Annual Non-Hour Costs: None.

The estimated burdens are itemized in the following table:

A. Type of response	B. Number of responses	C. Hours per response	D. Total hours (column B × column C)
Cooperative Range Improvement Agreement			
43 CFR 4120.3–2			
Form 4120–6 and related non-form information	500	2	1,000
Range Improvement Permit			
43 CFR 4120.3–3			
Form 4120–7 and related non-form information	30	2	60
Affected Public/Individuals and Households			
43 CFR 4120.5–1	50	1	50
Affected Public/Tribal, State, and County Agencies			
43 CFR 4120.5–2	530	1	530
Total	1,110		1,640

Jean Sonneman,

Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2016–24152 Filed 10–5–16; 8:45 am]

BILLING CODE 4310–84–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–557 and 731–TA–1312 (Final)]

Stainless Steel Sheet and Strip From China; Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–557 and 731–TA–1312 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of stainless steel sheet and strip from China, provided for in subheadings 7219.13.00, 7219.14.00, 7219.23.00, 7219.24.00, 7219.32.00, 7219.33.00, 7219.34.00, 7219.35.00, 7219.90.00, 7220.12.10, 7220.12.50, 7220.20.10, 7220.20.60, 7220.20.70, 7220.20.80, 7220.20.90, and 7220.90.00 of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce to be subsidized and sold at less-than-fair-value.

DATES: Effective September 19, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Szustakowski ((202) 205–3169), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by the Department of Commerce that certain benefits which constitute subsidies within the meaning of section 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in China of stainless steel sheet and strip, and that such products are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b).[1] The

[1] For purposes of these investigations, the Department of Commerce has defined the subject merchandise as ''stainless steel sheet and strip, whether in coils or straight lengths. Stainless steel

investigations were requested in petitions filed on February 12, 2016, by AK Steel Corp., West Chester, Ohio; Allegheny Ludlum, LLC, Pittsburgh, Pennsylvania; North American Stainless, Inc., Ghent, Kentucky; and Outokumpu Stainless USA, LLC, Bannockburn, Illinois.

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on January 17, 2017, and a public version will be issued thereafter, pursuant to section 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on Tuesday, January 31, 2017, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before January 25, 2017. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on January 30, 2017, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.23 of the Commission's rules; the deadline for filing is January 24, 2017. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.25 of the Commission's rules. The deadline for filing posthearing briefs is February 7, 2017. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before February 7, 2017. On February 24, 2017, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before February 28, 2017, but such final comments must not contain new factual information and must otherwise comply with section 207.30 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on E-Filing,* available on the Commission's Web site at *https://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: September 30, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–24060 Filed 10–5–16; 8:45 am]

BILLING CODE 7020–02–P

is an alloy steel containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. The subject sheet and strip is a flatrolled product with a width that is greater than 9.5 mm and with a thickness of 0.3048 mm and greater but less than 4.75 mm, and that is annealed or otherwise heat treated, and pickled or otherwise descaled. The subject sheet and strip may also be further processed (*e.g.,* cold-rolled, annealed, tempered, polished, aluminized, coated, painted, varnished, trimmed, cut, punched, or slit, etc.) provided that it maintains the specific dimensions of sheet and strip set forth above following such processing.'' For a full description of the scope of the investigations, including product exclusions, *see Countervailing Duty Investigation of Stainless Steel Sheet and Strip From the People's Republic of China: Preliminary Affirmative Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 81 FR 46643, July 18, 2016.

DEPARTMENT OF JUSTICE

[OMB Number 1110–0056]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; National Center for the Analysis of Violent Crime (NCAVC)

AGENCY: Department of Justice, Federal Bureau of Investigation.

ACTION: 60-day notice.

SUMMARY: The Department of Justice, Federal Bureau of Investigation, Critical Incident Response Group will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with established review procedures of the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until December 5, 2016.

FOR FURTHER INFORMATION CONTACT: All comments, suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Lesa Marcolini, Federal Bureau of Investigation, Critical Incident Response Group, Quantico, Virginia 22135.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. Type of Information Collection: Extension of a currently approved collection.

2. The Title of the Form/Collection: FBI–NCAVC Satisfaction Survey.

3. The agency form number, if any, and the applicable component of the Department sponsoring the collection: There is no agency form number applicable to this survey.

4. Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Federal, state, local, and tribal government law enforcement agencies to which the NCAVC has provided investigative assistance.

Abstract: The mission of the National Center for the Analysis of Violent Crime (NCAVC) combines investigative and operational support functions, research, and training in order to provide assistance, without charge, to law enforcement agencies investigating unusual or repetitive violent crimes. The NCAVC also provides support through expertise and consultation in non-violent matters such as national security, corruption, and white-collar crime investigations.

5. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: It is estimated that 100 respondents per calendar year will be contacted to complete a survey consisting of 11 questions. An approximate non-response rate of 50% is anticipated. It is estimated that a burden of approximately three to five minutes, or .05 to .08 hours, will be cast upon each respondent to complete the survey, with a total estimate of five to 8.3 hours in a calendar year for all respondents combined, if all respondents complete a survey. If the expected non-response rate of 50% holds true, then the combined burden estimate drops to approximately 2.5 to 4.2 hours per calendar year. The NCAVC estimates little to no variability within this time estimate based upon on individualized data retrieval systems, availability of requested data, and other variables, because this survey is intended to assess customer satisfaction rather than generate empirical data.

6. An estimate of the total public burden (in hours) associated with the collection: 20–32 annual burden hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: October 3, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–24166 Filed 10–5–16; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection: Leadership Engagement Survey

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: CORRECTION 60-day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until December 5, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Donna A. Rodriguez, Ph.D., Section Chief, Research and Analysis Staff, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* New collection.

2. *The Title of the Form/Collection:* Leadership Engagement Survey (LES).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Online survey.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public is Drug Enforcement Administration contractors and Task Force Officers. The LES is an initiative mandated by the Acting Administrator, DEA, to assess and improve competencies and proficiency of leadership across the DEA.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that approximately 5000 respondents will complete the survey within approximately 45 minutes.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 3750 hours. It is estimated that respondents will take 45 minutes to complete the survey. In order to calculate the public burden for the survey, 45 minutes was multiplied by 5000 and divided by 60 which equals 3750 total annual burden hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: October 3, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–24169 Filed 10–5–16; 8:45 am]

BILLING CODE 4410–09–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–073)]

NASA Advisory Council; Institutional Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act (Pub. L. 92–463), the National Aeronautics and Space Administration announces a meeting of the Institutional Committee of the NASA Advisory Council (NAC). This committee reports to the NAC.

DATES: Wednesday, November 2, 2016, 9:00 a.m.—5:00 p.m.; Thursday, November 3, 2016, 8:30 a.m.–5:00 p.m.; and Friday, November 4, 2016, 8:30 a.m.–12:00 noon, Local Time.

ADDRESSES: NASA Headquarters, Glennan Conference Room 1Q39, 300 E Street SW., Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Todd Mullins, NAC Institutional Committee Executive Secretary, NASA Headquarters, Washington, DC 20546; phone: (202) 358–3831; email: *todd.mullins@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. This meeting is also available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the toll free access number (844) 467–6272 or toll access number (720) 259–6462, and then the numeric participant passcode: 180093 followed by the # sign. To join via WebEx on November 2, the web link is *https://nasa.webex.com/* , the meeting number is 995 643 981 and the password is Meeting2016! (Password is case sensitive.) To join via WebEx on November 3, the link is *https://nasa.webex.com/,* the meeting number is 992 722 198 and the password is Meeting2016! To join via WebEx on November 4, the link is *https://nasa.webex.com/,* the meeting number is 992 605 812 and the password is Meeting2016! (Password is case sensitive.) NOTE: If dialing in, please ''mute'' your telephone. The agenda for the meeting includes the following topics:

- Business Systems Assessment (BSA) Status
- BSA Human Capital Implementation Plan
- BSA Procurement Implementation Plan
- BSA Facilities Deep Dive
- NAC Institutional Committee Work Plan

Attendees will be requested to sign a register and to comply with NASA Headquarters security requirements, including the presentation of a valid picture ID before receiving access to NASA Headquarters. Due to the Real ID Act, Public Law 109–13, any attendees with driver's licenses issued from non-compliant states/territories must present a second form of ID. [Federal employee badge; passport; active military identification card; enhanced driver's license; U.S. Coast Guard Merchant Mariner card; Native American tribal document; school identification accompanied by an item from LIST C (documents that establish employment authorization) from the ''List of the Acceptable Documents'' on Form I–9]. Non-compliant states/territories are: American Samoa, Minnesota, Missouri, and Washington. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; passport information (number, country, telephone); visa information (number, type, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship and Permanent Residents (green card holders) can provide full name and citizenship status no less than 3 working days prior to the meeting by contacting Ms. Mary Dunn, via email at *mdunn@nasa.gov* or by telephone at (202) 358–2789. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2016–24229 Filed 10–5–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL CREDIT UNION ADMINISTRATION

Submission for OMB Review; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice.

SUMMARY: The National Credit Union Administration (NCUA) will be submitting the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before November 7, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory

Affairs, Office of Management and Budget, Attention: Desk Officer for NCUA, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) NCUA PRA Clearance Officer, 1775 Duke Street, Alexandria, VA 22314, Suite 5067, or email at *PRAComments@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by emailing *PRAComments@ncua.gov* or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0108.

Type of Review: Extension of a previously approved collection.

Title: Monitoring Bank Secrecy Act Compliance, 12 CFR 748.2.

Abstract: Section 748.2 of NCUA's regulations, directs credit unions to establish a Bank Secrecy Act (BSA) compliance program that maintains procedures designed to assure and monitor compliance with the requirement of 31 U.S.C., Chap. 53, Subchapter II (sec. 5301–5329), the Bank Secrecy Act (31 U.S.C. 5318(g)), and 31 CFR Chapter X (parts 1000–1099), Financial Crimes Enforcement Network, Department of the Treasury. Each federally insured credit union (FICU) must develop and provide for the continued administration of a BSA compliance program to assure and monitor compliance with the recordkeeping and recording requirements prescribed by the BSA. At a minimum, a compliance program shall provide for a system of internal controls, independent testing for compliance, designation of an individual responsible for coordinating and monitoring day-to-day compliance; and training. NCUA examiners review the program to determine whether the credit union's procedures comply with all BSA requirements.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 95,264.

OMB Number: 3133–0146.

Type of Review: Extension of a previously approved collection.

Title: Production of Non-public Records and Testimony of Employees in Legal Proceedings (Touhy Request).

Abstract: Title 12 CFR part 792, subpart C, requires anyone requesting NCUA non-public records for use in legal proceedings, or similarly the testimony of NCUA personnel, to provide NCUA with information regarding the requester's grounds for the request. This process is also known as a ''Touhy Request''. The information collected will help the NCUA decide whether to release non-public records or permit employees to testify in legal proceedings.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 40.

OMB Number: 3133–0181.

Type of Review: Reinstatement of a previously approved collection.

Title: Registration of Mortgage Loan Originators

Abstract: The Secure and Fair Enforcement for Mortgage Licensing Act (S.A.F.E. Act), 12 U.S.C. 5101 *et seq.,* as codified by 12 CFR part 1007, requires an employee of a bank, savings association, or credit union or a subsidiary regulated by a Federal banking agency or an employee of an institution regulated by the Farm Credit Administration (FCA), (collectively, Agency-regulated Institutions) who engages in the business of a residential mortgage loan originator (MLO) to register with the Nationwide Mortgage Licensing System and Registry (Registry) and obtain a unique identifier. Agency-regulated institutions must also adopt and follow written policies and procedures to assure compliance with the S.A.F.E. Act. The Registry is intended to aggregate and improve the flow of information to and between regulators; provide increased accountability and tracking of mortgage loan originators; enhance consumer protections; reduce fraud in the residential mortgage loan origination process; and provide consumers with easily accessible information at no charge regarding the employment history of, and the publicly adjudicated disciplinary and enforcement actions against MLOs.

Affected Public: Individuals or households; Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 76,204.

By John Brolin, Acting Secretary of the Board, the National Credit Union Administration, on October 3, 2016.

Dated: October 3, 2016.

Dawn D. Wolfgang,

NCUA PRA Clearance Officer.

[FR Doc. 2016–24223 Filed 10–5–16; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Mathematical and Physical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

NAME: Advisory Committee for Mathematical and Physical Sciences (#66).

DATE/TIME: November 17, 2016; 8:30 a.m.–5:00 p.m.
November 18, 2016; 8:30 a.m.–12:00 p.m.

PLACE: National Science Foundation 4201 Wilson Blvd., Arlington, VA 22230. Board Room (room 1235); visitors should request a visitor's badge as instructed on the meeting Web site: *http://www.nsf.gov/events/event_summ.jsp?cntn_id=136042&org=MPS.*

TYPE OF MEETING: Open.

CONTACT PERSON: John Gillaspy, National Science Foundation, 4201 Wilson Boulevard, Suite 1005, Arlington, Virginia 22230; Telephone: 703/292–8300.

PURPOSE OF MEETING: To provide advice, recommendations and counsel on major goals and policies pertaining to mathematical and physical sciences programs and activities.

AGENDA

Thursday, November 17, 2016

8:30 a.m.–8:45 a.m. Meeting opening, FACA briefing and approval of meeting minutes
8:45 a.m.–10:000 a.m. Science Hors D'Oeuvre and MPS updates
10:00 a.m.–10:15 a.m. Break
10:15 a.m.–1:30 p.m. NSF Big Ideas
1:30 p.m.–2:30 p.m. Division of Mathematical Sciences Committee of Visitors report
2:30 p.m.–3:15 p.m. NSF Merit Review Process
3:15 p.m.–3:30 p.m. Break
3:30 p.m.–4:15 p.m. NSF Strategic Review Planning
4:15 p.m.–5:30 p.m. Preparation for meeting with the NSF Chief Operating Officer

Friday, November 18th, 2016

8:30 a.m.–8:45 a.m. Meeting opening
8:45 a.m.–9:45 a.m. Robust and Reliable Sciences
9:45 a.m.–10:00 a.m. Break
10:00 a.m.–11:00 a.m. Meeting with NSF Chief Operating Officer
11:00 a.m.–12:00 p.m. General Comments and Discussions
12:00 p.m. Adjourn

Dated: October 3, 2016.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2016–24176 Filed 10–5–16; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0001]

Sunshine Act Meeting Notice

DATE: Week of October 3, 2016.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

Week of October 3, 2016

Wednesday, October 5, 2016

8:55 a.m. Affirmation Session (Public Meeting) (Tentative)

U.S. Department of Energy (Export of 93.20% Enriched Uranium) (Petition Seeking Leave to Intervene and Request for Hearing) (Tentative).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

* * * * *

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

* * * * *

Additional Information

By a vote of 3–0 on October 3, 2016, the Commission determined pursuant to U.S.C. 552b(e) and '9.107(a) of the Commission's rules that the above referenced Affirmation Session be held with less than one week notice to the public. The meeting is scheduled on October 5, 2016.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: October 3, 2016.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2016–24389 Filed 10–4–16; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2008–0252]

Vogtle Electric Generating Plant, Units 3 and 4

AGENCY: Nuclear Regulatory Commission.

ACTION: Determination of the successful completion of inspections, tests, and analyses.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) staff has determined that the inspections, tests, and analyses have been successfully completed, and that the specified acceptance criteria are met for multiple inspections, tests, analyses, and acceptance criteria (ITAAC) for the Vogtle Electric Generating Plant (VEGP), Units 3 and 4.

ADDRESSES: Please refer to Docket ID NRC–2008–0252 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0252. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Chandu Patel, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3025; email: *Chandu.Patel@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Licensee Notification of Completion of ITAAC

Southern Nuclear Operating Company, Inc. (SNC), Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC., MEAG Power SPVJ, LLC., MEAG Power SPVP, LLC., and the City of Dalton, Georgia, (hereafter called the licensee) has submitted ITAAC closure notifications (ICNs) under § 52.99(c)(1) of title 10 of the *Code of Federal Regulations* (10 CFR), informing the NRC that the licensee has successfully performed the required inspections, tests, and analyses, and that the acceptance criteria are met for:

VEGP Unit 3 ITAAC

2.1.02.08a.ii (29), 2.2.03.08c.vi.01 (189), 2.2.03.08c.vi.02 (190), 2.5.01.03c (513), 2.5.02.13 (552), and E.3.9.05.01.05 (853)

VEGP Unit 4 ITAAC

2.1.02.08a.ii (29), 2.2.03.08c.vi.01 (189), 2.2.03.08c.vi.02 (190), 2.5.01.03c (513), and 2.5.02.13 (552)

The ITAAC for VEGP Unit 3 are in Appendix C of the VEGP Unit 3 combined license (ADAMS Accession No. ML14100A106). The ITAAC for VEGP Unit 4 are in Appendix C of VEGP Unit 4 combined license (ADAMS Accession No. ML14100A135).

II. NRC Staff Determination of Completion of ITAAC

The NRC staff has determined that the specified inspections, tests, and analyses have been successfully completed, and that the specified acceptance criteria are met. The documentation of the NRC staff's

determination is in the ITAAC Closure Verification Evaluation Form (VEF) for each ITAAC. The VEF is a form that represents the NRC staff's structured process for reviewing ICNs. Each ICN presents a narrative description of how the ITAAC was completed. The NRC's ICN review process involves a determination on whether, among other things: (1) Each ICN provides sufficient information, including a summary of the methodology used to perform the ITAAC, to demonstrate that the inspections, tests, and analyses have been successfully completed; (2) each ICN provides sufficient information to demonstrate that the acceptance criteria of the ITAAC are met; and (3) any NRC inspections for the ITAAC have been completed and any ITAAC findings associated with that ITAAC have been closed.

The NRC staff's determination of the successful completion of these ITAAC is based on information available at this time and is subject to the licensee's ability to maintain the condition that the acceptance criteria are met. If the staff receives new information that suggests the staff's determination on any of these ITAAC is incorrect, then the staff will determine whether to reopen that ITAAC (including withdrawing the staff's determination on that ITAAC). The NRC staff's determination will be used to support a subsequent finding, pursuant to 10 CFR 52.103(g), at the end of construction that all acceptance criteria in the combined license are met. The ITAAC closure process is not finalized for these ITAAC until the NRC makes an affirmative finding under 10 CFR 52.103(g). Any future updates to the status of these ITAAC will be reflected on the NRC's Web site at *http://www.nrc.gov/reactors/new-reactors/oversight/itaac.html*.

This notice fulfills the staff's obligations under 10 CFR 52.99(e)(1) to publish a notice in the **Federal Register** of the NRC staff's determination of the successful completion of inspections, tests and analyses.

Vogtle Electric Generating Plant Unit 3, Docket No. 5200025

A complete list of the review status for VEGP Unit 3 ITAAC, including the submission date and ADAMS Accession Number for each ICN received, the ADAMS Accession Number for each VEF, and the ADAMS Accession Numbers for the inspection reports associated with these specific ITAAC, can be found on the NRC's Web site at *http://www.nrc.gov/reactors/new-reactors/new-licensing-files/vog3-icnsr.pdf*.

Vogtle Electric Generating Plant Unit 4, Docket No. 5200026

A complete list of the review status for VEGP Unit 4 ITAAC, including the submission date and ADAMS Accession Number for each ICN received, the ADAMS Accession Number for each VEF, and the ADAMS Accession Numbers for the inspection reports associated with these specific ITAAC, can be found on the NRC's Web site at *http://www.nrc.gov/reactors/new-reactors/new-licensing-files/vog4-icnsr.pdf*.

Dated at Rockville, Maryland, this 29th day of September 2016.

For the Nuclear Regulatory Commission.

Jennifer Dixon-Herrity,

Acting Chief, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–24192 Filed 10–5–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–09091; NRC–2011–0148]

Strata Energy, Inc.; Ross Uranium In-Situ Recovery Facility; Source and Byproduct Materials License

AGENCY: Nuclear Regulatory Commission.

ACTION: Record of decision; update.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued an updated Record of Decision (ROD) related to the license for Strata Energy, Inc. (Strata), Ross Uranium *In-Situ* Recovery (ISR) Facility in Crook County, Wyoming. Strata's request for a source and byproduct materials license for the Ross ISR facility was contested through the NRC's adjudicatory process. On June 29, 2016, the Commission denied a petition for review of the Atomic Safety and Licensing Board's (ASLB) decision. The ROD has been updated to account for the ASLB's decision and the Commission's ruling.

DATES: The ROD was updated as of September 28, 2016.

ADDRESSES: Please refer to Docket ID NRC–2011–0148 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2011–0148. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin WBA Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Jessie Muir-Quintero, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–7476; email: *Jessie.Muir-Quintero@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC issued a license to Strata for its Ross ISR Facility in Crook County, Wyoming in April 2014. Along with the issuance of the license, the NRC published a ROD that supported its decision to approve Strata's license application for the Ross ISR Facility.

After the license was issued, the NRC's ASLB, an independent, trial-level adjudicatory body, granted a hearing request from joint intervenors, the Natural Resources Defense Council and the Powder River Basin Resource Council. The ASLB held an evidentiary hearing from September 30, 2014, through October 1, 2014, for three admitted contentions on environmental matters related to the licensing of the Ross ISR Facility. In its initial decision following the hearing, the ASLB ruled in favor of Strata and the NRC on all three contentions. In doing so, the ASLB supplemented the ROD to include a revised license condition (10.12) and additional analyses that were placed on the record by various parties. In June 2016, the Commission denied a petition for review of the ASLB's decision. The NRC's initial ROD was published on April 24, 2014. The updated ROD

accounts for the ASLB's decision and the Commission's ruling.

II. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

Item No.	Document title	ADAMS Accession No.
1	Generic Environmental Impact Statement for *In-Situ* Leach Uranium Milling Facilities, May 2009	ML091530075
2	Strata Energy, Inc., Materials License Application, January 4, 2011	ML110120063
3	Supplemental Information, February 28, 2011	ML110800187
4	ASLB Decision, February 10, 2012	ML12041A295
5	Response to Request for Additional Information, March 30, 2012	ML121030404
6	Response to Request for Additional Information, April 6, 2012	ML121020343
7	Clarification to RAI Responses, August 10, 2012	ML12227A369
8	Technical Report Replacement Pages, January 18, 2013	ML130370654
9	Containment Barrier Wall Construction Update, October 14, 2013	ML13295A230
10	Safety Evaluation Report Suggested Corrections, October 17, 2013	ML13296A026
11	Technical Report Replacement Pages, February 19, 2014	ML14051A020
12	Environmental Impact Statement for the Ross ISR Project in Crook County, Wyoming, Supplement to the Generic Environmental Impact Statement for *In-Situ* Leach Uranium Milling Facilities, Draft Report for Public Comments, March 31, 2013.	ML13078A036
13	Environmental Impact Statement for the Ross ISR Project in Crook County, Wyoming, Supplement to the Generic Environmental Impact Statement for *In-Situ* Leach Uranium Milling Facilities, Final Report, February 28, 2014.	ML14056A096
14	Programmatic Agreement for Protection of Cultural Resources, April 2014	ML14111A346
15	NRC Safety Evaluation Report, April 18, 2014	ML14108A088
16	Source and Byproduct Materials License SUA–1601, April 24, 2014	ML14069A315
17	NRC Staff's Record of Decision, April 24, 2014	ML14073A107
18	Natural Resource Defense Council's Powder River Basin Resource Council's Petition for Review of Atomic Safety and Licensing Board's January 23, 2015 Initial Decision Denying Environmental Contentions 1 Through 3, and Interlocutory Decisions Denying Environmental Contentions 4/5 and 6/7, February 17, 2015.	ML15048A103
19	ASLB Decision, January 23, 2015	ML15023A566
20	Commission Decision, CLI–16–13 Memorandum and Order, June 29, 2016	ML16181A107
21	NRC Staff's Updated Record of Decision, September 28, 2016	ML16230A021

Dated at Rockville, Maryland, this 28th day of September 2016.

For the Nuclear Regulatory Commission.

Craig G. Erlanger,

Director, Division of Fuel Cycle Safety, Safeguards and Environmental Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2016–24196 Filed 10–5–16; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2016–149; CP2016–166; MC2016–211 and CP2016–300; MC2016–212 and CP2016–301]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 11, 2016 (Comment due date applies to all Docket Nos. listed above)

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2016–149; *Filing Title:* Notice of United States Postal Service of Amendment to First-Class Package Service Contract 51, with Portions Filed Under Seal; *Filing Acceptance Date:* September 30, 2016; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Erin Mahagan; *Comments Due:* October 11, 2016.

2. *Docket No(s).:* CP2016–166; *Filing Title:* Notice of the United States Postal Service of Filing Modification Two to a Global Reseller Expedited Package Contracts 2 Negotiated Service Agreement; *Filing Acceptance Date:* September 30, 2016; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* October 11, 2016.

3. *Docket No(s).:* MC2016–211 and CP2016–300; *Filing Title:* Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 34 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* September 30, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Erin Mahagan; *Comments Due:* October 11, 2016.

4. *Docket No(s).:* MC2016–212 and CP2016–301; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Contract 244 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* September 30, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Kenneth R. Moeller; *Comments Due:* October 11, 2016.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–24219 Filed 10–5–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* October 6, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 30, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 244 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–212, CP2016–301.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–24145 Filed 10–5–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Temporary Emergency Committee of the Board of Governors; Sunshine Act Meeting

DATES AND TIMES: Tuesday, October 11, 2016, at 4:00 p.m.

PLACE: Teleconference.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Tuesday, October 11, 2016, at 4:00 p.m.

1. Strategic Issues.
2. Financial Matters.
3. Pricing.
4. Personnel Matters and Compensation Issues.
5. Executive Session—Discussion of prior agenda items and Board governance.

GENERAL COUNSEL CERTIFICATION: The General Counsel of the United States Postal Service has certified that the meeting may be closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Julie S. Moore, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW., Washington, DC 20260–1000. Telephone: (202) 268–4800.

Julie S. Moore,

Secretary.

[FR Doc. 2016–24261 Filed 10–4–16; 11:15 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* October 6, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 30, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 34 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–211, CP2016–300.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–24144 Filed 10–5–16; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79013; File No. SR–ISEGemini–2016–12]

Self-Regulatory Organizations; ISE Gemini, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a New Rule 209

September 30, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2016, ISE Gemini, LLC (''ISE Gemini'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a new Rule 209 entitled, ''Collection of Exchange Fees and Other Claims'' to require Members to provide a clearing account number at the National Securities Clearing Corporation (''NSCC'') for purposes of permitting the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Exchange to debit any undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to the Exchange.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to collect undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to the Exchange through NSCC.[3] This proposal will provide a cost savings to the Exchange in that it will alleviate administrative processes related to the collection of monies owed to the Exchange.[4] Collection matters divert staff resources away from the Exchange's regulatory and business purposes. In addition, the debiting process will prevent Member accounts from becoming overdue. The Exchange notes that it has a billing dispute policy.

The Exchange proposes to adopt new Rule 209 and require Members, and all applicants for registration as such to provide a clearing account number for an account at NSCC for purposes of permitting the Exchange to debit any undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to the Exchange or other charges related to Rules 205 and 206.[5]

The Exchange will send a monthly invoice[6] to each Member on approximately the 4th–6th business day of the following month.[7] The Exchange will also send a file to NSCC each month on approximately the 23rd of the following month to initiate the debit of the appropriate amount stated on the Member's invoice for the prior month. Because the Members will receive an invoice well before any monies are debited (normally within two weeks), the Members will have adequate time to contact the staff with any questions concerning their invoice. If a Member disputes an invoice, the Exchange will not include the disputed amount in the debit if the Member has disputed the amount in writing to the Exchange's designated staff by the 15th of the month, or the following business day if the 15th is not a business day, and the amount in dispute is at least $10,000 or greater.

Once NSCC receives the file from the Exchange, NSCC would proceed to debit the amounts indicated from the Clearing Members' account. In the instance where the Member clears through an Exchange Clearing Member, the estimated transactions fees owed to the Exchange are reconciled daily by the Clearing Member to ensure adequate funds have been escrowed. The Exchange would debit any monies owed including undisputed or final fees,[8] fines, charges and/or other monetary sanctions or monies due and owing to the Exchange.[9]

The Exchange proposes this rule change become operative on October 1, 2016. On November 23, 2016, the Exchange will debit October 2016 billing pursuant to the process described in this rule change.[10] The Exchange will notify Members of this rule change to provide its Members ample time to provide the Exchange with the information necessary for the direct debit and prepare for the change to the collection process.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5) of the Act,[12] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest by providing Members with an efficient process to pay undisputed or final fees, fines, charges and/or monetary sanctions or monies dues and owing to the Exchange.

The Exchange believes that its proposal to debit NSCC accounts is reasonable because it would ease the Member's administrative burden in paying monthly invoices, avoid overdue balances and provide same day collection from all Members who owe monies to the Exchange. The Exchange has a billing dispute policy. The Member may dispute the invoice prior to the debit. This policy also lowers the Exchange's administrative costs because staff resources would not be diverted to review of untimely requests regarding billing.

The Exchange believes that its proposal to debit NSCC accounts is equitable and not unfairly discriminatory because it will apply to all Members in a uniform manner. Today, the debit process is applied at all Nasdaq exchanges.[13]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. With this

[3] The Exchange will not debit accounts for fees that are unusually large or for special circumstances, unless such debiting is requested by the Member.

[4] Today, some fees are collected through The Options Clearing Corporation, but not all fees.

[5] *See* ISE Gemini Rules 205 (Participant Fees) and 206 (Liability for Payment of Fees).

[6] The monthly invoice will indicate that the amount on the invoice will be debited from the designated NSCC account. Each month, the Exchange will send a file to the Member's clearing firm which will indicate the amounts to be debited from each Member. If a Member is ''self-clearing,'' no such file would be sent as the Member would receive the invoice, as noted above, which would indicate the amount to be debited.

[7] By way of example, October invoices would be sent on November 7th.

[8] Exchange fees are noted on the Exchange Fee Schedule.

[9] This includes, among other things, fines which result from the imposition of fines pursuant to Rules 1611, Judgment and Sanction; and 1614, Imposition of Fines for Minor Rules Violations. With respect to disciplinary sanctions that are imposed by either the Business Conduct Committee or a Hearing Panel, the Exchange would not debit any monies until such action is final. The Exchange would not consider an action final until all appeal periods have run and/or all appeal timeframes are exhausted. With respect to non-disciplinary actions, the Exchange would similarly not take action to debit a Member account until all appeal periods have run and/or all appeal timeframes are exhausted. Any uncontested disciplinary or non-disciplinary actions will be debited, and the amount due will appear on the Member's invoice prior to the actual NSCC debit.

[10] The initial debit will include all outstanding fees through October 1, 2016.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *See* NASDAQ Phlx LLC Rule 909, The NASDAQ Stock Market LLC Rule 7007, NASDAQ Options Market LLC Rules at Chapter XV, Section 1, NASDAQ BX, Inc. Rule 7011 and BX Option Rules at Chapter XV, Section 1 (collectively ''Nasdaq exchanges'').

proposal, the proposed debit process would apply uniformly to all Members.

Further, this proposal would provide a cost savings to the Exchange in that it would alleviate administrative processes related to the collection of monies owed to the Exchange. Collection matters divert staff resources away from the Exchange's regulatory and business purposes. In addition, the debiting process would prevent Member accounts from becoming overdue.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii) [16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. In its filing with the Commission, the Exchange requests that the Commission waive the 30-day operative delay. The Exchange proposes that the proposed rule change become operative on October 1, 2016. On November 23, 2016, the Exchange would debit October 2016 billing pursuant to the process set forth in the proposed rule change. The Exchange represents that waiver of the 30-day operative delay would allow it to conform its billing processes similar to the process in place at the various Nasdaq exchanges.[17] The Exchange notes that all ISE Gemini Members have an NSCC account or have a clearing firm with an NSCC account. Direct debit is an options industry standard. According to the Exchange, all members should be able to provide ISE Gemini with an NSCC account prior to the date of the November 23, 2016 debit. Further, the Exchange believes that this process will alleviate administrative processes related to the collection of monies owed to the Exchange. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission designates the proposed rule change to be operative upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ISEGemini–2016–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISEGemini–2016–12. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISEGemini–2016–12 and should be submitted on or before October 27, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–24148 Filed 10–5–16; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] *See supra* note 13.

[18] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–32299]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

September 30, 2016.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of September 2016. A copy of each application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be

received by the SEC by 5:30 p.m. on October 25, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: The Commission: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Hae-Sung Lee, Attorney-Adviser, at (202) 551–7345 or Chief Counsel's Office at (202) 551–6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE., Washington, DC 20549–8010.

Altegris KKR Commitments Fund [File No. 811–22964]

Summary: Applicant, a closed-end investment company and a feeder fund in a master/feeder structure, seeks an order declaring that it has ceased to be an investment company. On May 31, 2016, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of approximately $37,218 incurred in connection with the liquidation were paid by applicant.

Filing Date: The application was filed on August 17, 2016.

Applicant's Address: 1200 Prospect Street, Suite 400, La Jolla, CA 92037.

Morgan Stanley Limited Duration U.S. Government Trust [File No. 811–06330]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has transferred its assets to Short Duration Income Portfolio, a series of Morgan Stanley Institutional Fund Trust, and on January 11, 2016, made a final distribution to its shareholders based on net asset value. Expenses of $132,277 incurred in connection with the reorganization were paid by applicant.

Filing Date: The application was filed on August 22, 2016.

Applicant's Address: c/o Morgan Stanley Investment Management Inc., 522 Fifth Avenue, New York, New York 10036.

DoubleLine Equity Funds [File No. 811–22790]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On March 30, 2016, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of approximately $10,000 incurred in connection with the liquidation were paid by applicant's investment adviser.

Filing Date: The application was filed on August 26, 2016.

Applicant's Address: 333 South Grand Avenue, Suite 1800, Los Angeles, CA 90071.

Whitebox Mutual Funds [File No. 811–22574]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On January 19, 2016, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of approximately $140,000 incurred in connection with the liquidation were paid by applicant's investment adviser.

Filing Date: The application was filed on August 26, 2016.

Applicant's Address: 3033 Excelsior Boulevard, Suite 300, Minneapolis, MN 55416.

Dreyfus/Laurel Tax-Free Municipal Funds [File No. 811–03700]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On October 28, 2015, applicant made a liquidating distribution to its shareholders, based on net asset value. Applicant incurred no expenses in connection with the liquidation.

Filing Dates: The application was filed on August 8, 2016, and amended on August 31, 2016.

Applicant's Address: c/o The Dreyfus Corporation, 200 Park Avenue, New York, NY 10166.

A&Q Event Fund LLC [File No. 811–10479]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On February 5, 2016 and May 6, 2016, applicant made liquidating distributions to its shareholders, based on net asset value. Expenses of $11,000 incurred in connection with the liquidation were paid by applicant.

Filing Date: The application was filed on September 2, 2016.

Applicant's Address: c/o UBS Hedge Fund Solutions LLC, 600 Washington Boulevard, Stamford, Connecticut 06901.

A&Q Aggregated Alpha Strategies Fund LLC [File No. 811–21516]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On February 5, 2016 and May 5, 2016, applicant made liquidating distributions to its shareholders, based on net asset value. Expenses of $11,000 incurred in connection with the liquidation were paid by applicant.

Filing Date: The application was filed on September 2, 2016.

Applicant's Address: c/o UBS Hedge Fund Solutions LLC, 600 Washington Boulevard, Stamford, Connecticut 06901.

A&Q Equity Opportunity Fund LLC [File No. 811–10527]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has transferred its assets to A&Q Masters Fund and, on January 1, 2016, made a final distribution to its shareholders based on net asset value. Expenses of approximately $263,083 incurred in connection with the reorganization were paid by applicant's investment adviser.

Filing Date: The application was filed on September 2, 2016.

Applicant's Address: c/o UBS Hedge Fund Solutions LLC, 600 Washington Boulevard, Stamford, Connecticut 06901.

Purisima Funds [File No. 811–07737]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On June 30, 2016, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of approximately $20,000 incurred in connection with the liquidation were paid by applicant.

Filing Date: The application was filed on September 7, 2016.

Applicant's Address: 5525 NW Fisher Creek Drive, Camas, WA 98607.

BlackRock Municipal Bond Investment Trust [File No. 811–21054]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to BlackRock Municipal Income Investment Trust, and on June 1, 2016, final distributions were paid to applicant's shareholders based on net asset value. Expenses of approximately $261,735 incurred in connection with the reorganization were paid by applicant and applicant's investment adviser.

Filing Date: The application was filed on September 8, 2016.

Applicant's Address: 100 Bellevue Parkway, Wilmington, Delaware 19809.

Redmond Reinsurance Investment Interval Fund [File No. 811–23041]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Date: The application was filed on September 15, 2016.

Applicant's Address: 101 East Lancaster Avenue, Suite 201, Wayne, PA 19087.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Brent J. Fields,

Secretary.

[FR Doc. 2016–24150 Filed 10–5–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79014; File No. SR–ISE–2016–24]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a New Rule 213

September 30, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2016, the International Securities Exchange, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a new Rule 213 entitled, ''Collection of Exchange Fees and Other Claims'' to require Members to provide a clearing account number at the National Securities Clearing Corporation (''NSCC'') for purposes of permitting the Exchange to debit any undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to the Exchange.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to collect undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to the Exchange through NSCC.[3] This proposal will provide a cost savings to the Exchange in that it will alleviate administrative processes related to the collection of monies owed to the Exchange.[4] Collection matters divert staff resources away from the Exchange's regulatory and business purposes. In addition, the debiting process will prevent Member accounts from becoming overdue. The Exchange notes that it has a billing dispute policy.

The Exchange proposes to adopt new Rule 213 and require Members, and all applicants for registration as such to provide a clearing account number for an account at NSCC for purposes of permitting the Exchange to debit any undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to the Exchange or other charges related to Rules 205, 206, 207, 208, 209, and 210.[5]

The Exchange will send a monthly invoice[6] to each Member on approximately the 4th–6th business day of the following month.[7] The Exchange will also send a file to NSCC each month on approximately the 23rd of the following month to initiate the debit of the appropriate amount stated on the Member's invoice for the prior month. Because the Members will receive an invoice well before any monies are debited (normally within two weeks), the Members will have adequate time to contact the staff with any questions concerning their invoice. If a Member disputes an invoice, the Exchange will not include the disputed amount in the debit if the Member has disputed the amount in writing to the Exchange's designated staff by the 15th of the month, or the following business day if the 15th is not a business day, and the amount in dispute is at least $10,000 or greater.

Once NSCC receives the file from the Exchange, NSCC would proceed to debit the amounts indicated from the Clearing Members' account. In the instance where the Member clears through an Exchange Clearing Member, the estimated transactions fees owed to the Exchange are reconciled daily by the Clearing Member to ensure adequate funds have been escrowed. The Exchange would debit any monies owed including undisputed or final fees,[8] fines, charges and/or other monetary sanctions or monies due and owing to the Exchange.[9]

The Exchange proposes this rule change become operative on October 1, 2016. On November 23, 2016, the Exchange will debit October 2016 billing pursuant to the process described in this rule change.[10] The

[3] The Exchange will not debit accounts for fees that are unusually large or for special circumstances, unless such debiting is requested by the Member.

[4] Today, some fees are collected through The Options Clearing Corporation, but not all fees.

[5] *See* ISE Rules 205 (Access Fees), 206 (Transaction Fees), 207 (Communication Fees), 208 (Regulatory Fees or Charges), 209 (Transfer Fees) and 210 (Liability for Payment of Fees).

[6] The monthly invoice will indicate that the amount on the invoice will be debited from the designated NSCC account. Each month, the Exchange will send a file to the Member's clearing firm which will indicate the amounts to be debited from each Member. If a Member is ''self-clearing,'' no such file would be sent as the Member would receive the invoice, as noted above, which would indicate the amount to be debited.

[7] By way of example, October invoices would be sent on November 7th.

[8] Exchange fees are noted on the Exchange Fee Schedule.

[9] This includes, among other things, fines which result from the imposition of fines pursuant to Rules 1611, Judgment and Sanction; and 1614, Imposition of Fines for Minor Rules Violations. With respect to disciplinary sanctions that are imposed by either the Business Conduct Committee or a Hearing Panel, the Exchange would not debit any monies until such action is final. The Exchange would not consider an action final until all appeal periods have run and/or all appeal timeframes are exhausted. With respect to non-disciplinary actions, the Exchange would similarly not take action to debit a Member account until all appeal periods have run and/or all appeal timeframes are exhausted. Any uncontested disciplinary or non-disciplinary actions will be debited, and the amount due will appear on the Member's invoice prior to the actual NSCC debit.

[10] The initial debit will include all outstanding fees through October 1, 2016.

Exchange will notify Members of this rule change to provide its Members ample time to provide the Exchange with the information necessary for the direct debit and prepare for the change to the collection process.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5) of the Act,[12] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest by providing Members with an efficient process to pay undisputed or final fees, fines, charges and/or monetary sanctions or monies dues and owing to the Exchange.

The Exchange believes that its proposal to debit NSCC accounts is reasonable because it would ease the Member's administrative burden in paying monthly invoices, avoid overdue balances and provide same day collection from all Members who owe monies to the Exchange. The Exchange has a billing dispute. [sic] The Member may dispute the invoice prior to the debit. This policy also lowers the Exchange's administrative costs because staff resources would not be diverted to review of untimely requests regarding billing.

The Exchange believes that its proposal to debit NSCC accounts is equitable and not unfairly discriminatory because it will apply to all Members in a uniform manner. Today, the debit process is applied at all Nasdaq exchanges.[13]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. With this proposal, the proposed debit process would apply uniformly to all Members.

Further, this proposal would provide a cost savings to the Exchange in that it would alleviate administrative processes related to the collection of monies owed to the Exchange. Collection matters divert staff resources away from the Exchange's regulatory and business purposes. In addition, the debiting process would prevent Member accounts from becoming overdue.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii)[16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. In its filing with the Commission, the Exchange requests that the Commission waive the 30-day operative delay. The Exchange proposes that the proposed rule change become operative on October 1, 2016. On November 23, 2016, the Exchange would debit October 2016 billing pursuant to the process set forth in the proposed rule change. The Exchange represents that waiver of the 30-day operative delay would allow it to conform its billing processes similar to the process in place at the various Nasdaq exchanges.[17] The Exchange notes that all ISE Members have an NSCC account or have a clearing firm with an NSCC account. Direct debit is an options industry standard. According to the Exchange, all members should be able to provide ISE with an NSCC account prior to the date of the November 23, 2016 debit. Further, the Exchange believes that this process will alleviate administrative processes related to the collection of monies owed to the Exchange. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission designates the proposed rule change to be operative upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2016–24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2016–24. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *See* NASDAQ Phlx LLC Rule 909, The NASDAQ Stock Market LLC Rule 7007, NASDAQ Options Market LLC Rules at Chapter XV, Section 1, NASDAQ BX, Inc. Rule 7011 and BX Option Rules at Chapter XV, Section 1 (collectively ''Nasdaq exchanges.'')

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] *See supra* note 13.

[18] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2016–24 and should be submitted on or before October 27, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–24147 Filed 10–5–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79017; File No. SR–NYSEARCA–2016–123]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Partial Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Partial Amendment No. 1, Amending Rule 7.46 Relating to the Exchange's Order Types To Implement the Tick Size Pilot Program

September 30, 2016.

I. Introduction

On August 25, 2016, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to: (1) Change system functionality to implement the Plan to Implement a Tick Size Pilot Program (''Plan'' or ''Pilot'')[3] submitted to the Commission pursuant to Rule 608 of Regulation NMS[4] under the Act; (2) clarify the operation of certain exceptions to the Trade-at Prohibition[5] on Pilot Securities in Test Group Three; (3) amend the Limit Up/Limit Down (''LULD'') price controls pursuant to the Regulation NMS Plan to Address Extraordinary Market Volatility (''LULD Plan'');[6] and (4) amend the Exchange's limit order price protection rule. The proposed rule change was published for comment in the **Federal Register** on September 15, 2016.[7] The Commission received two comment letters in response to the Notice.[8] On September 27, 2016, the Exchange filed a partial amendment to the proposed rule change (''Amendment No. 1'').[9]

This order provides notice of filing of Amendment No. 1 and approves the proposal, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Amended Proposal

The Exchange proposes to: (1) Change system functionality to implement the Plan; (2) clarify the operation of certain exceptions to the Trade-at Prohibition on Pilot Securities in Test Group Three; (3) amend the LULD price controls pursuant to the LULD Plan; and (4) amend the Exchange's limit order price protection rule.

A. Amendments to System Functionality To Implement the Plan

1. Trade-at Intermarket Sweep Orders (''TA ISO'')[10]

The Exchange proposes to accept TA ISOs in all securities. Further, TA ISOs must be designated as Immediate or Cancel (''IOC''), may be designated with a ''no midpoint execution'' modifier, may not be designated with a minimum trade size, and do not route. TA ISO would be immediately traded with contra-side displayed and non-displayed interest in the NYSE Arca Book up to its full size and limit price and the quantity not so traded will be immediately and automatically cancelled.

2. Permitted Price Increment for Pilot Securities[11]

The Exchange proposes that references in Exchange rules to the minimum price variation (''MPV'')[12] would mean $0.05 instead of the current $0.01 for Pilot Securities in Test Groups One, Two, and Three. Further, references to truncating to the MPV in Exchange rules would mean rounding down to the applicable quoting MPV for Pilot Securities in Test Groups One, Two, and Three. Mid-Point Liquidity Orders[13] must be entered with a limit price in a $0.05 pricing increment.

3. Rejection of Market Pegged Orders in Pilot Securities[14]

The Exchange proposes that Market Pegged Orders[15] will be rejected for all Pilot Securities.

4. Retail Price Improvement Orders Increment[16]

The Exchange proposes that for Test Group Two and Test Group Three, Retail Price Improvement Orders[17]

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[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) (''Approval Order''). Unless otherwise specified, capitalized terms used in this rule filing are defined as set forth in the Plan.

[4] 17 CFR 242.608.

[5] Exchange Rule 7.46(e)(4)(A) defines the ''Trade-at Prohibition'' to mean the prohibition against executions by a Trading Center of a sell order for a Pilot Security at the price of a Protected Bid or the execution of a buy order for a Pilot Security at the price of a Protected Offer during regular trading hours. *See also* Plan Section I(LL) and Plan Section VI(D).

[6] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (File No. 4–631).

[7] Securities Exchange Act Release No. 78801 (September 9, 2016), 81 FR 63525 (''Notice'').

[8] *See* Letters from Eric Swanson, EVP, General Counsel, Bats Global Markets, Inc., Elizabeth K. King, General Counsel and Corporate Secretary, New York Stock Exchange; and Thomas A. Wittman, EVP, Global Head of Equities, Nasdaq, Inc., dated September 9, 2016 (''Comment Letter No. 1''); and Eric Swanson, EVP, General Counsel, Bats Global Markets, Inc., dated September 12, 2016 (''Comment Letter No. 2'').

[9] In Amendment No. 1, the Exchange proposes to do the following: (1) Delete the proposal to amend Rule 7.35P because the Exchange recently filed a separate proposed rule change to make the same amendment, which is now operative. *See* Securities Exchange Act Release No. 78861 (September 16, 2016) (SR–NYSEArca–2016–129) (''Rule 7.35P Filing''); (2) modify Rule 7.46(f)(3) to provide that Market Pegged Orders in all Pilot Securities would be rejected and delete references to Market Pegged Orders in Rule 7.46(f)(5)(H); and (3) correct typographical errors in the original proposal.

[10] *See* proposed Exchange Rule 7.46(f)(1).

[11] *See* proposed Exchange Rule 7.46(f)(2).

[12] *See* Exchange Rule 7.6 for a definition of the MPV.

[13] A Mid-Point Liquidity Order is a Limit Order that is not displayed, does not route, and has with a working price at the midpoint of the PBBO. *See* Exchange Rule 7.31P(d)(3).

[14] *See* proposed Exchange Rule 7.46(f)(3). *See also* Amendment No. 1.

[15] A Market Pegged Order is an order to buy (sell) with a working price that is pegged to the PBO (PBB). *See* Exchange Rule 7.31P(h). A Market Pegged Order to buy (sell) will be rejected on arrival, or cancelled when resting, if there is no PBO (PBB) against which to peg. Market Pegged Orders will not participate in any auctions. Market Pegged Orders are not displayed and are ranked ''Priority 3—Non-Display Orders.'' A Market Pegged Order to buy (sell) may include an offset value that will set the working price below (above) the PBO (PBB) by a specified offset.

[16] *See* proposed Exchange Rule 7.46(f)(4).

[17] A Retail Price Improvement Order consists of non-displayed interest in NYSE Arca-listed

must be entered in pricing increments of $0.005.

5. Trading in Test Group Three Pilot Securities

a. Change in Priority [18]

The Exchange proposes to revise the priority of resting orders [19] for Pilot Securities in Test Group Three, as follows: (A) First priority would be given to ''Priority 2—Display Orders,'' which are non-marketable Limit Orders with a displayed working price; (B) second priority would be given to ''protected quotations of Away Markets [20];'' (C) third priority would be given to ''Priority 1—Market Orders,'' which are unexecuted Market Orders; and (D) fourth priority would be given to ''Priority 3—Non-Display Orders,'' which are non-marketable Limit Orders for which the working price is not displayed, including reserve interest of Reserve Orders.

b. Routing to Away Markets [21]

The Exchange proposes that for Pilot Securities in Test Group Three, orders would not be routed to Away Markets that are not displaying Protected Quotations.

c. Repricing of Limit Orders [22]

The Exchange proposes to assign a working price equal to the re-priced display price in Test Group Three for displayed limit orders to avoid ranking orders undisplayed at the price of a Protected Quotation. The Exchange currently assigns a display price of a displayed Limit Order one MPV below (above) the contra-side PBO (PBB), and a working price equal to the contra-side PBBO to prevent locking or crossing the PBBO.[23]

d. Non-Displayed Portion of Reserve Orders [24]

The Exchange proposes that for Pilot Securities in Test Group Three, if a Reserve Order [25] to buy (sell) is displayed at a price that is locked or crossed by a protected offer (bid), the non-displayed portion of the Reserve Order would be assigned a working price of $0.05 below (above) the protected offer (bid), but if routable, would route to a protected offer (bid) based on the limit price of the order.

e. Limit Non-Displayed Orders [26]

The Exchange proposes that for Pilot Securities in Test Group Three, a Limit Non-Displayed Order would be assigned a working price one MPV away from the PBBO. Currently, if the limit price of a Limit Non-Displayed Order to buy (sell) is equal to the PBO (PBB), the order will be assigned a working price equal to the limit price, *i.e.,* the same price as the PBO (PBB).[27]

f. Orders That Do Not Route [28]

The Exchange proposes changes to how orders with instructions do not route would interact with the NYSE Arca Book. These orders include: ''Arca Only Orders,'' [29] ''ALO Orders,'' [30] and ''Intermarket Sweep Orders.'' [31] The Exchange proposes that on arrival, orders that do not route would trade with resting orders in the NYSE Arca Book, consistent with the terms of the order and the Trade-at Prohibition. Day ISOs, on arrival, would be eligible for the Trade-at Intermarket Sweep Orders exception to the Trade-at Prohibition. An IOC ISO to buy (sell) would not trade with orders to sell (buy) ranked ''Priority 1—Market Orders'' or ''Priority 3—Non-Display Orders'' that are the same price as a protected offer (bid) unless the limit price of such IOC ISO is higher (lower) than the price of the protected offer (bid).

For Arca Only Order or ALO Orders, the Exchange proposes that when being added to the NYSE Arca Book, such orders to buy (sell) with a limit price equal to or above (below) the PBO (PBB) would be assigned a display price and working price one MPV below (above) the PBO (PBB). Once the Arca Only Order or ALO Order to buy (sell) is resting on the NYSE Arca Book, such orders would not be eligible to trade with later-arriving orders to sell (buy) ranked ''Priority 2—Display Orders'' priced equal to the PBO (PBB). A later-arriving order to buy (sell) that is eligible to trade with the PBO (PBB) may trade before such resting order.

g. Block Size Exception to the Trade-at Prohibition [32]

The Exchange proposes that the only orders eligible for the block size exception to the Trade-at Prohibition would be Limit IOC Cross Orders [33] that meet the Block Size definition. A Limit IOC Cross Order that is at the same price as the PBBO but does not meet the Block Size definition would be rejected in Test Group Three.

h. Rejection of Tracking Orders [34]

The Exchange proposes that Tracking Orders [35] will be rejected for Test Group Three Pilot Securities.

B. Limit Up–Limit Down (''LULD'') Price Bands

The Exchange proposes that after the Exchange opens or reopens an Exchange-listed security but before receiving Price Bands from the Securities Information Processor (''SIP'') under the LULD Plan, the Exchange would calculate Price Bands based on the first Reference Price provided to the SIP and, if such Price Bands are not in the MPV for the security, round such Price Bands to the nearest price at the applicable MPV.

C. Limit Order Price Protection

The Exchange proposes to specify that the limit order price protection for both buy and sell orders that are not in the MPV for the security would be rounded down to the nearest price at the applicable MPV.

D. Miscellaneous Changes

The Exchange proposes to add the phrase ''or Intermarket Sweep Orders'' to the definition of ''Trade-at ISO'' as well as into the Trade-at ISO exception to the Trade-at Prohibition to clarify that ISOs may be routed to execute against

securities and UTP Securities, excluding NYSE-listed (Tape A) securities, that would trade at prices better than the PBB or PBO by at least $0.001 and that is identified as such. *See* Exchange Rule 7.44P(a)(4).

[18] *See* proposed Exchange Rule 7.46(f)(5)(A).

[19] Exchange Rule 7.36P(e) sets forth the priority of orders for all securities.

[20] See Exchange Rule 1.1(ffP).

[21] *See* proposed Exchange Rule 7.46(f)(5)(B).

[22] *See* proposed Exchange Rule 7.46(f)(5)(C).

[23] *See* Exchange Rule 7.31P(a)(2)(C).

[24] *See* proposed Exchange Rule 7.46(f)(5)(D).

[25] A Reserve Order is defined as a limit or inside limit order with a quantity of the size displayed and with a reserve quantity of the size (''reserve interest'') that is not displayed. *See* Exchange Rule 7.31P(d)(1).

[26] *See* proposed Exchange Rule 7.46(f)(5)(E).

[27] *See* Rule 7.31P(d)(2)(A).

[28] *See* proposed Exchange Rule 7.46(f)(5)(F).

[29] An ''Arca Only Order'' is a limit order that does not route. *See* Exchange Rule 7.31P(e)(1).

[30] An ''ALO Order'' is an Arca Only Order that, with some exceptions, will not remove liquidity from the NYSE Arca Book and must have a minimum on one displayed round lot. *See* Exchange Rule 7.31P(e)(2).

[31] An ''Intermarket Sweep Order'' is a Limit Order that does not route and meets the requirements of Rule 600(b)(30) of Regulation NMS. *See* Exchange Rule 7.31P(e)(3).

[32] *See* proposed Exchange Rule 7.46(f)(5)(G).

[33] A Limit IOC Cross Order is a two-sided order with instructions to match the buy-side with the identified sell-side at a specified price and that does not route and will cancel at the time of entry if the cross price is not between the BBO or would trade through the PBBO. *See* Exchange Rule 7.31P(g)(1).

[34] *See* proposed Exchange Rule 7.46(f)(5)(H).

[35] A Tracking Order is an order to buy (sell) with a limit price that is not displayed, does not route, must be entered in round lots and designated Day, and will trade only with an order to sell (buy) that is eligible to route. The working price of a Tracking Order to buy (sell) is the PBB (PBO), provided that such price is at or below (above) the limit price of the Tracking Order. *See* Exchange Rule 7.31P(d)(4).

the full displayed size of the Protected Quotation that was traded at.[36]

The Exchange proposes to amend the Block Size exception to the Trade-at Prohibition to allow a Block Size order to execute on multiple Trading Centers for the purpose of compliance with Rule 611 of Regulation NMS.[37]

Finally, the Exchange proposes to correct numerous typographical errors in the proposed rule text.

III. Summary of Comment Letters

Both comment letters express support for the proposed rule change and suggest that the Commission should approve the proposal. In Comment Letter No. 1, the commenters stated that if the proposal is approved as proposed, then NYSE would be able to meet the October 3, 2016 implementation date. Further, in Comment Letter No. 1, the commenters stated their belief that the requirements from the Commission have been unclear. In Comment Letter No. 2, the commenter questioned Commission staff's authority.

IV. Discussion and Commission's Findings

After careful review of the proposed rule change, as modified by Amendment No. 1, and the comment letters, the Commission finds that the proposal, as modified by Amendment No. 1, is consistent with the requirements of the Act, Rule 608 of Regulation NMS,[38] and the rules and regulations thereunder that are applicable to a national securities exchange.[39] Specifically, the Commission finds that the rule change is consistent with Section 6(b)(5) of the Act,[40] which requires that the rules of a national securities exchange be designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As noted in the Approval Order, the Plan is by design, an objective, data-driven test to evaluate how a wider tick size would impact trading, liquidity, and market quality of securities of smaller capitalization companies. In addition, the Plan is designed with three Test Groups and a Control Group, to allow analysis and comparison of incremental market structure changes on the Pilot Securities and is designed to produce empirical data that could inform future policy decisions.

The Exchange proposes changes to modify how the Exchange will handle orders during the Pilot Period. Specifically, the Exchange proposes to accept TA ISOs in all securities, to specify how references to MPV should be considered for Pilot Securities in the Test Groups, to require that MPL Orders with a limit price must be entered in a $0.05 pricing increment for Pilot Securities in the Test Groups, to reject Market Pegged Orders[41] and to specify the pricing increment for Retail Price Improvement Orders in Test Groups Two and Three. The Exchange further proposes changes for Pilot Securities in Test Group Three to comply with the Trade-at Prohibition, including a different priority for execution of resting orders, how display price and working price would be determined for certain Limit Orders, Reserve Orders and Non-Displayed Limit Orders, how orders that do not route would operate, and that Tracking Orders would be rejected for Test Group Three Pilot Securities. In addition, the Exchange proposes to not route to Away Markets that are not displaying Protected Quotations. Finally, the Exchange proposes to only permit Limit IOC Cross Orders that meet the Block Size definition to be eligible for the Block Size exception to the Trade-at Prohibition.[42]

The Commission believes that these changes are reasonably designed to comply with the Plan. Further, the Commission believes that the proposed changes that are targeted at particular Test Groups are necessary for compliance with the Plan. Accordingly, the Commission finds that these changes are consistent with Section 6(b)(5) of the Act[43] and Rule 608 of Regulation NMS[44] because they implement the Plan and clarify Exchange Rules.

In addition, the Exchange proposes to adopt a rule to specify how the Exchange will calculate LULD Price Bands after the Exchange opens or reopens. The Commission believes that this change should help to ensure that trading does not occur outside of Price Bands when LULD is in effect.

Finally, the Exchange proposes to specify that if Limit Order Price Protection is not in the MPV it would be rounded down to the nearest price at the applicable MPV. The Commission believes that this change should provide clarity in the Exchange's rules.

For these reasons, the Commission finds that the proposed rule change, as modified by Amendment No.1, is consistent with the requirements of the Act and Rule 608 of Regulation NMS.

V. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2016–123 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR- NYSEArca-2016–123. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be

[36] *See* proposed Exchange Rules 7.46(a)(1)(D)(ii) and 7.46(e)(4)(C)(x).

[37] *See* proposed Exchange Rule 7.46(e)(4)(C)(iii).

[38] 17 CFR 242.608.

[39] In approving this rule change, the Commission has considered the rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[40] 15 U.S.C. 78f(b)(5).

[41] *See* Amendment No. 1. The Exchange originally proposed to reject Market Pegged Orders only in Test Group Three. The Commission believes that the amendment to reject all Market Pegged Orders in Pilot Securities modifies the proposal so that it does not cause a disparate impact on different Test Groups and the Control Group.

[42] The Commission notes that the Limit IOC Cross Orders that meet the definition of Block Size must also satisfy the provisions of the Block Size exception, including that it may not be an aggregation of non-block orders, or broken into orders small than Block Size prior to submitting the order to a Trading Center for execution. *See* NYSE Acra Rule 7.46(e)(4)(C).

[43] 15 U.S.C. 78f(b)(5).

[44] 17 CFR 242.608.

available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–123 and should be submitted on or before October 27, 2016.

VI. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice of the proposed rule change, as modified by Amendment No. 1 in the **Federal Register**. As described above, the Exchange proposes to amend its rules to comply with the Plan and clarify other rules related to LULD and Limit Order Price Protection.

The Commission believes that the proposals to clarify how LULD Price Bands that are calculated by the Exchange would be rounded in instances where they are not in the MPV for a security and how Limit Order Price Protection would be rounded in instances where it is not in the MPV for a security provides clarity in the Exchange rules.

In addition, the Commission notes that the Pilot is scheduled to start on October 3, 2016, and accelerated approval of the proposal would ensure that the rules of the Exchange would be in place for the start of the Pilot. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Exchange Act,[45] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VII. Conclusion

It is therefore ordered that, pursuant to Section 19(b)(2) of the Act,[46] that the proposed rule change (SR–NYSEArca–2016–123), as modified by Amendment No. 1, be and hereby is, approved on an accelerated basis.

[45] 15 U.S.C. 78s(b)(2).

[46] *Id.*

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[47]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–24146 Filed 10–5–16; 8:45 am]

BILLING CODE 8011–01–P

[47] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79012; File No. SR–ISEMercury–2016–18]

Self-Regulatory Organizations; ISE Mercury, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a New Rule 209

September 30, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 28, 2016, ISE Mercury, LLC (''ISE Mercury'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a new Rule 209 entitled, ''Collection of Exchange Fees and Other Claims'' to require Members to provide a clearing account number at the National Securities Clearing Corporation (''NSCC'') for purposes of permitting the Exchange to debit any undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to the Exchange.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to collect undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to the Exchange through NSCC.[3] This proposal will provide a cost savings to the Exchange in that it will alleviate administrative processes related to the collection of monies owed to the Exchange.[4] Collection matters divert staff resources away from the Exchange's regulatory and business purposes. In addition, the debiting process will prevent Member accounts from becoming overdue. The Exchange notes that it has a billing dispute policy.

The Exchange proposes to adopt new Rule 209 and require Members, and all applicants for registration as such to provide a clearing account number for an account at NSCC for purposes of permitting the Exchange to debit any undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to the Exchange or other charges related to Rules 205 and 206.[5]

The Exchange will send a monthly invoice[6] to each Member on approximately the 4th–6th business day of the following month.[7] The Exchange will also send a file to NSCC each month on approximately the 23rd of the following month to initiate the debit of the appropriate amount stated on the Member's invoice for the prior month. Because the Members will receive an invoice well before any monies are debited (normally within two weeks), the Members will have adequate time to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange will not debit accounts for fees that are unusually large or for special circumstances, unless such debiting is requested by the Member.

[4] Today, some fees are collected through The Options Clearing Corporation, but not all fees.

[5] *See* ISE Mercury Rules 205 (Participant Fees) and 206 (Liability for Payment of Fees).

[6] The monthly invoice will indicate that the amount on the invoice will be debited from the designated NSCC account. Each month, the Exchange will send a file to the Member's clearing firm which will indicate the amounts to be debited from each Member. If a Member is ''self-clearing'', no such file would be sent as the Member would receive the invoice, as noted above, which would indicate the amount to be debited.

[7] By way of example, October invoices would be sent on November 7th.

contact the staff with any questions concerning their invoice. If a Member disputes an invoice, the Exchange will not include the disputed amount in the debit if the Member has disputed the amount in writing to the Exchange's designated staff by the 15th of the month, or the following business day if the 15th is not a business day, and the amount in dispute is at least $10,000 or greater.

Once NSCC receives the file from the Exchange, NSCC would proceed to debit the amounts indicated from the Clearing Members' account. In the instance where the Member clears through an Exchange Clearing Member, the estimated transactions fees owed to the Exchange are reconciled daily by the Clearing Member to ensure adequate funds have been escrowed. The Exchange would debit any monies owed including undisputed or final fees,[8] fines, charges and/or other monetary sanctions or monies due and owing to the Exchange.[9]

The Exchange proposes this rule change become operative on October 1, 2016. On November 23, 2016, the Exchange will debit October 2016 billing pursuant to the process described in this rule change.[10] The Exchange will notify Members of this rule change to provide its Members ample time to provide the Exchange with the information necessary for the direct debit and prepare for the change to the collection process.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5) of the Act,[12] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest by providing Members with an efficient process to pay undisputed or final fees, fines, charges and/or monetary sanctions or monies dues and owing to the Exchange.

The Exchange believes that its proposal to debit NSCC accounts is reasonable because it would ease the Member's administrative burden in paying monthly invoices, avoid overdue balances and provide same day collection from all Members who owe monies to the Exchange. The Exchange has a billing dispute policy. The Member may dispute the invoice prior to the debit. This policy also lowers the Exchange's administrative costs because staff resources would not be diverted to review of untimely requests regarding billing.

The Exchange believes that its proposal to debit NSCC accounts is equitable and not unfairly discriminatory because it will apply to all Members in a uniform manner. Today, the debit process is applied at all Nasdaq exchanges.[13]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. With this proposal, the proposed debit process would apply uniformly to all Members.

Further, this proposal would provide a cost savings to the Exchange in that it would alleviate administrative processes related to the collection of monies owed to the Exchange. Collection matters divert staff resources away from the Exchange's regulatory and business purposes. In addition, the debiting process would prevent Member accounts from becoming overdue.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii)[16] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. In its filing with the Commission, the Exchange requests that the Commission waive the 30-day operative delay. The Exchange proposes that the proposed rule change become operative on October 1, 2016. On November 23, 2016, the Exchange would debit October 2016 billing pursuant to the process set forth in the proposed rule change. The Exchange represents that waiver of the 30-day operative delay would allow it to conform its billing processes similar to the process in place at the various Nasdaq exchanges.[17] The Exchange notes that all ISE Mercury Members have an NSCC account or have a clearing firm with an NSCC account. Direct debit is an options industry standard. According to the Exchange, all members should be able to provide ISE Mercury with an NSCC account prior to the date of the November 23, 2016 debit. Further, the Exchange believes that this process will alleviate administrative processes related to the collection of monies owed to the Exchange. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission designates the proposed rule change to be operative upon filing.[18]

[8] Exchange fees are noted on the Exchange Fee Schedule.

[9] This includes, among other things, fines which result from the imposition of fines pursuant to Rules 1611, Judgment and Sanction; and 1614, Imposition of Fines for Minor Rules Violations. With respect to disciplinary sanctions that are imposed by either the Business Conduct Committee or a Hearing Panel, the Exchange would not debit any monies until such action is final. The Exchange would not consider an action final until all appeal periods have run and/or all appeal timeframes are exhausted. With respect to non-disciplinary actions, the Exchange would similarly not take action to debit a Member account until all appeal periods have run and/or all appeal timeframes are exhausted. Any uncontested disciplinary or non-disciplinary actions will be debited, and the amount due will appear on the Member's invoice prior to the actual NSCC debit.

[10] The initial debit will include all outstanding fees through October 1, 2016.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *See* NASDAQ Phlx LLC Rule 909, The NASDAQ Stock Market LLC Rule 7007, NASDAQ Options Market LLC Rules at Chapter XV, Section 1, NASDAQ BX, Inc. Rule 7011 and BX Option Rules at Chapter XV, Section 1 (collectively ''Nasdaq exchanges'').

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] *See supra* note 13.

[18] For purposes only of waiving the 30-day operative delay, the Commission also has

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ISEMercury–2016–18 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISEMercury–2016–18. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISEMercury–2016–18 and should be submitted on or before October 27, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–24149 Filed 10–5–16; 8:45 am]

BILLING CODE 8011–01–P

considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 9746]

International Security Advisory Board (ISAB) Meeting Notice

In accordance with section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App 10(a)(2), the Department of State announces a meeting of the International Security Advisory Board (ISAB) to take place on November 30, 2016, at the Department of State, Washington, DC.

Pursuant to section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. App 10(d), and 5 U.S.C. 552b(c)(1), it has been determined that this Board meeting will be closed to the public because the Board will be reviewing and discussing matters properly classified in accordance with Executive Order 13526. The purpose of the ISAB is to provide the Department with a continuing source of independent advice on all aspects of arms control, disarmament, nonproliferation, political-military affairs, international security, and related aspects of public diplomacy. The agenda for this meeting will include classified discussions related to the Board's studies on current U.S. policy and issues regarding arms control, international security, nuclear proliferation, and diplomacy.

For more information, contact Christopher Herrick, Executive Director of the International Security Advisory Board, U.S. Department of State, Washington, DC 20520, telephone: (202) 647–9683.

Dated: September 23, 2016.

Christopher Herrick,

Executive Director, International Security Advisory Board, U.S. Department of State.

[FR Doc. 2016–24210 Filed 10–5–16; 8:45 am]

BILLING CODE 4710–27–P

DEPARTMENT OF STATE

[Public Notice 9747]

U.S. Department of State Advisory Committee on Private International Law (ACPIL): Public Meeting on the Judgments Project

The Office of the Assistant Legal Adviser for Private International Law, Department of State, gives notice of a public meeting to discuss the judgments project. The public meeting will take place on Tuesday, November 15, 2016, from 10:00 a.m. until 12:30 p.m. EST. This is not a meeting of the full Advisory Committee.

A Special Commission of the Hague Conference met in June 2016 to discuss the structure and the provisions of a draft convention on the recognition and enforcement of foreign judgments in civil and commercial matters. Another Special Commission of the Hague Conference is scheduled to meet in February 2017 to continue the drafting process.

The purpose of the public meeting is to obtain the views of interested stakeholders on the current draft provisions of the convention, located at *https://assets.hcch.net/docs/* to discuss certain matters such as scope, possible declarations to the convention, and general and final clauses.

Time and Place: The meeting will take place from 10:00 a.m. until 12:30 p.m. EST on November 15, 2016, in Room 240, South Building, State Department Annex 4, Washington, DC 20037. Participants should plan to arrive at the Navy Hill gate on the west side of 23rd Street NW. (at the intersection of 23rd Street NW. and D Street NW.) by 9:30 a.m. for visitor screening. If you are unable to attend the public meeting and would like to participate from a remote location, teleconferencing will be available. Those who cannot attend but wish to comment are welcome to do so by email to John Kim at *kimmjj@state.gov* or Mike Dennis at *dennismj@state.gov.*

Public Participation: This meeting is open to the public, subject to the capacity of the meeting room. Access to the building is strictly controlled. For pre-clearance purposes, those planning to attend should email *pil@state.gov* providing full name, address, date of

birth, citizenship, driver's license or passport number, and email address. This information will greatly facilitate entry into the building. A member of the public needing reasonable accommodation should email *pil@state.gov* not later than November 9, 2016. Requests made after that date will be considered, but might not be able to be fulfilled. If you would like to participate by telephone, please email *pil@state.gov* to obtain the call-in number and other information.

Data from the public is requested pursuant to Public Law 99–399 (Omnibus Diplomatic Security and Antiterrorism Act of 1986), as amended; Public Law 107–56 (USA PATRIOT Act); and Executive Order 13356. The purpose of the collection is to validate the identity of individuals who enter Department facilities.

The data will be entered into the Visitor Access Control System (VACS–D) database. Please see the Security Records System of Records Notice (State–36) at *https://foia.state.gov/_docs/SORN/State-36.pdf* for additional information.

Dated: September 16, 2016.

Michael J. Dennis,

Attorney-Adviser, Office of Private International Law, Office of the Legal Adviser, U.S. Department of State.

[FR Doc. 2016–24211 Filed 10–5–16; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

[Public Notice: 9748]

Advisory Committee on International Economic Policy; Notice of Open Meeting

The Advisory Committee on International Economic Policy (ACIEP) will meet from 2:00 until 5:00 p.m., on Tuesday, October 25, in New York City at 383 Madison Avenue, 13th floor, Conference Room 1311; New York, NY. The meeting will be hosted by the Assistant Secretary of State for Economic and Business Affairs, Charles H. Rivkin, and Committee Chair Paul R. Charron. The ACIEP serves the U.S. Government in a solely advisory capacity, and provides advice concerning topics in international economic policy. It is expected that during this meeting, the ACIEP subcommittees on sanctions policy and the Stakeholder Advisory Board will provide updates on their recent work.

This meeting is open to the public, though seating is limited. Entry to the building is controlled. To obtain pre-clearance for entry, members of the public planning to attend must, *no later than Friday, October 14,* provide their full name and professional affiliation to Alan Krill by email: *KrillA@state.gov.* Requests for reasonable accommodation should be made to Alan Krill before Friday, October 14. Requests made after that date will be considered, but might not be possible to fulfill.

For additional information, contact Alan Krill, Bureau of Economic and Business Affairs, at (202) 647–2231, or *KrillA@state.gov.*

Dated: September 26, 2016.

Alan Krill,

Designated Federal Officer, U.S. Department of State.

[FR Doc. 2016–24212 Filed 10–5–16; 8:45 am]

BILLING CODE 4710–AE–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36046]

CSX Transportation, Inc.—Trackage Rights Exemption—Grand Trunk Western Railroad Company

Grand Trunk Western Railroad Company (GTW), pursuant to a written trackage rights agreement (Agreement),[1] has agreed to grant CSX Transportation, Inc. (CSXT), overhead trackage rights: (1) Between GTW's connection to CSXT at Wellsboro, Ind., at or near milepost 71.1, and Griffith, Ind., at or near milepost 36.1, on GTW's South Bend Subdivision, and (2) between Griffith, Ind., at or near milepost 36.1, and Munster, Ind., at or near milepost 30.92, on GTW's Elsdon Subdivision, a distance of approximately 40.18 miles, including all sidings, yard tracks and yard leads now existing or hereafter constructed along those tracks (the Line).[2]

CSXT proposes to use the Line to move a limited volume of traffic between CSXT's lines that connect with the Line at Munster, Ind., on the west and Wellsboro, Ind., on the east, which CSXT states will result in operating economies and improved service. CSXT will be permitted to operate up to four trains a day, unless otherwise agreed between GTW and CSXT.

CSXT states that the Agreement does not contain interchange commitments.

The transaction is scheduled to be consummated on or shortly after October 20, 2016, the effective date of the exemption (30 days after the verified notice of exemption was filed).

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed by October 13, 2016 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36046, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Louis E. Gitomer, Law Offices of Louis E. Gitomer, LLC, 600 Baltimore Avenue, Suite 301, Towson, MD 21204.

According to CSXT, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our Web site at ''*WWW.STB.GOV.*''

Decided: October 3, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2016–24187 Filed 10–5–16; 8:45 am]

BILLING CODE 4915–01–P

[1] An executed redacted copy of the Agreement between GTW and CSXT was filed with the notice of exemption. An unredacted copy was filed under seal along with a motion for protective order pursuant to 49 CFR 1104.14(b). That motion will be addressed in a separate decision.

[2] In a letter filed on September 27, 2016, CSXT corrects the description of the territory in which it proposes to operate.

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Limitation on Claims Against Proposed Public Transportation Projects

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: This notice announces final environmental actions taken by the Federal Transit Administration (FTA) for projects in the City of Baton Rouge, Parish of East Baton Rouge, LA, and Hennepin County, MN. The purpose of this notice is to announce publicly the environmental decisions by FTA on the

subject projects and to activate the limitation on any claims that may challenge these final environmental actions.

DATES: By this notice, FTA is advising the public of final agency actions subject to Section 139(l) of Title 23, United States Code (U.S.C.). A claim seeking judicial review of FTA actions announced herein for the listed public transportation projects will be barred unless the claim is filed on or before March 6, 2017.

FOR FURTHER INFORMATION CONTACT: Nancy-Ellen Zusman, Assistant Chief Counsel, Office of Chief Counsel, (312) 353–2577 or Terence Plaskon, Environmental Protection Specialist, Office of Environmental Programs, (202) 366–0442. FTA is located at 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 9:00 a.m. to 5:00 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FTA has taken final agency actions by issuing certain approvals for the public transportation projects listed below. The actions on the projects, as well as the laws under which such actions were taken, are described in the documentation issued in connection with the projects to comply with the National Environmental Policy Act (NEPA) and in other documents in the FTA administrative record for the projects. Interested parties may contact either the project sponsor or the relevant FTA Regional Office for more information. Contact information for FTA's Regional Offices may be found at *https://www.fta.dot.gov.*

This notice applies to all FTA decisions on the listed projects as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to, NEPA [42 U.S.C. 4321–4375], Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303], Section 106 of the National Historic Preservation Act [16 U.S.C. 470f], and the Clean Air Act [42 U.S.C. 7401–7671q]. This notice does not, however, alter or extend the limitation period for challenges of project decisions subject to previous notices published in the **Federal Register**. The projects and actions that are the subject of this notice are:

1. *Project name and location:* TramLinkBR Project, City of Baton Rouge, Parish of East Baton Rouge, LA. *Project sponsor:* City of Baton Rouge, Parish of East Baton Rouge. *Project description:* The proposed project would construct a modern tram (streetcar) system located in an approximately three-mile north-south corridor linking the State Capitol and downtown area of the City of Baton Rouge with Louisiana State University and the Old South Baton Rouge neighborhood. The project would include 11 stop locations, an overhead contact system, four traction power substations, and an operations and maintenance facility. *Final agency actions:* No use determination of Section 4(f) resources; Section 106 finding of no adverse effect; and Finding of No Significant Impact, dated July 29, 2016. *Supporting documentation:* Environmental Assessment, dated June 3, 2016.

2. *Project name and location:* METRO Blue Line Light Rail Transit Extension Project, Hennepin County, MN. *Project sponsor:* Metropolitan Council. *Project description:* The proposed project is approximately 13.5 miles of new double-track extension of the METRO Blue Line that will connect downtown Minneapolis to the cities of Golden Valley, Robbinsdale, Crystal, and Brooklyn Park. The alignment includes 11 new light rail stations, approximately 1,670 additional park-and-ride spaces, accommodations for passenger drop-off and bicycle and pedestrian access, and new or restructured local bus routes connecting stations to nearby residential, commercial, and educational land uses. The project would include one operations and maintenance facility, 17 traction power substations, 25 signal bungalow sites, seven new light rail transit bridges, and five reconstructed roadway bridges. *Final agency actions:* Section 4(f) determination; a Section 106 Memorandum of Agreement, dated August 23, 2016; project-level air quality conformity; and a Record of Decision, dated September 19, 2016. *Supporting documentation:* Final Environmental Impact Statement, dated July 15, 2016.

Lucy Garliauskas,

Associate Administrator Planning and Environment.

[FR Doc. 2016–24216 Filed 10–5–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Unblocking of Specially Designated Nationals and Blocked Persons, Executive Order 12978

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the name of an individual whose property and interests in property has been unblocked pursuant to Executive Order 12978 of October 21, 1995, ''Blocking Assets and Prohibiting Transactions With Significant Narcotics Traffickers''.

DATES: The unblocking and removal from the list of Specially Designated Nationals and Blocked Persons (SDN List) of the individual identified in this notice whose property and interests in property were blocked pursuant to Executive Order 12978 of October 21, 1995, is effective on September 29, 2016.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Department of the Treasury, Office of Foreign Assets Control, Washington, DC 20220, Tel: (202) 622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site at (*www.treasury.gov/ofac*).

Background

On October 21, 1995, the President, invoking the authority, *inter alia,* of the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) (IEEPA), issued Executive Order 12978 (60 FR 54579, October 24, 1995) (the Order). In the Order, the President declared a national emergency to deal with the threat posed by significant foreign narcotics traffickers centered in Colombia and the harm that they cause in the United States and abroad.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in the United States, or that hereafter come within the United States or that are or hereafter come within the possession or control of United States persons, of: (1) The foreign persons listed in an Annex to the Order; (2) any foreign person determined by the Secretary of Treasury, in consultation with the Attorney General and the Secretary of State: (a) To play a significant role in international narcotics trafficking centered in Colombia; or (b) to materially assist in, or provide financial or technological support for or goods or services in support of, the narcotics trafficking activities of persons designated in or pursuant to the Order; and (3) persons determined by the Secretary of the Treasury, in consultation with the Attorney General

and the Secretary of State, to be owned or controlled by, or to act for or on behalf of, persons designated pursuant to the Order.

On September 29, 2016, the Associate Director of the Office of Global Targeting removed from the SDN List the individual listed below, whose property and interests in property were blocked pursuant to the Order:

RICARDO DIAZ, Alfonso, Calle 15 No. 10–52, La Union, Valle, Colombia; c/o CASA GRAJALES S.A., La Union, Valle, Colombia; c/o CRETA S.A., La Union, Valle, Colombia; c/o FREXCO S.A., La Union, Valle, Colombia; c/o HEBRON S.A., Tulua, Valle, Colombia; c/o WORLD WORKING COMERCIALIZADORA INTERNACIONAL S.A., Cali, Colombia; c/o FUNDACION CENTRO FRUTICOLA ANDINO, La Union, Valle, Colombia; Cedula No. 14950952 (Colombia) (individual) [SDNT].

Dated: September 29, 2016.

Gregory T. Gatjanis,

Associate Director, Office of Global Targeting, Office of Foreign Assets Control.

[FR Doc. 2016–24186 Filed 10–5–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Unblocking of Specially Designated Nationals and Blocked Persons, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of four individuals and five entities whose property and interests in property have been unblocked pursuant to the Foreign Narcotics Kingpin Designation Act (Kingpin Act) (21 U.S.C. Sections 1901–1908, 8 U.S.C. Section 1182).

DATES: The unblocking and removal from the list of Specially Designated Nationals and Blocked Persons (SDN List) of the individuals and entities identified in this notice whose property and interests in property were blocked pursuant to the Kingpin Act, is effective on September 29, 2016.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Department of the Treasury Office of Foreign Assets Control, Washington, DC 20220, Tel: (202) 622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site at (*www.treasury.gov/ofac*).

Background

On December 3, 1999, the Kingpin Act was signed into law by the President of the United States. The Kingpin Act provides a statutory framework for the President to impose sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and to the benefits of trade and transactions involving U.S. persons and entities.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President or the Secretary of the Treasury. In addition, the Secretary of the Treasury consults with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security when designating and blocking the property or interests in property, subject to U.S. jurisdiction, of persons or entities found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; and/or (3) playing a significant role in international narcotics trafficking.

On September 29, 2016, the Associate Director of the Office of Global Targeting removed from the SDN List the individuals and entities listed below, whose property and interests in property were blocked pursuant to the Kingpin Act.

Individuals

1. AZIMI, Haji Mohammad Rafi (a.k.a. AZIMI, Haji Muhammad Rafi; a.k.a. RAFI, Abdul); DOB 15 Feb 1972; POB Afghanistan; citizen Afghanistan; Passport OR131106 (Afghanistan) (individual) [SDNTK].

2. GUBEREK GRIMBERG, Felipe, Panama; Safed, Israel; DOB 26 Jun 1968; POB Bogota, Colombia; Cedula No. 80414317 (Colombia); alt. Cedula No. E–8–83638 (Panama); National ID No. 326930153 (Israel) (individual) [SDNTK] (Linked To: I&S HOLDING COMPANY, S.A.; Linked To: INDUITEX LTDA.; Linked To: INVERSIONES GILFE S.A.; Linked To: ORBITAL HORIZONS CORP.; Linked To: FUNDACION ISSARA; Linked To: COMERCIALIZADORA INTERNACIONAL ANDINA LIMITADA; Linked To: GUBEREK GRIMBERG E HIJOS Y CIA. S. EN C.; Linked To: CONSTRUCTORA NACIONAL DE PANAMA S.A.; Linked To: AVANTI JOYEROS E.U.; Linked To: COLOMBO PERUANA DE TEJIDOS S.A.).

3. HAKIMI, Ahmad Shah, c/o AHMAD SHAH MONEY EXCHANGE, Afghanistan; c/o MUSHTAQ SHAHEEN CONSTRUCTION AND ROAD MAKING COMPANY, Afghanistan; DOB 1971; Passport OA547045 (Afghanistan); alt. Passport TR039938 (Afghanistan) (individual) [SDNTK].

4. RODRIGUEZ BADILLO, Maria Paloma, Madrid, Spain; DOB 26 Jan 1968; POB Madrid, Spain; citizen Spain; D.N.I. 33503596–W (Spain) (individual) [SDNTK].

Entities

1. AHMAD SHAH MONEY EXCHANGE (a.k.a. AHMAD SHAH HAKIMI MONEY EXCHANGE; a.k.a. HAKIMI MONEY EXCHANGE; a.k.a. SHAH HAKIMI MONEY EXCHANGE), Surai Shahzada, Ground Floor, Shop No. 7, Kabul, Afghanistan; Sara-e-Shahzada Market, Shop No. 7, Kabul, Afghanistan; Sarayee Shahzada, 1 floor, Shop No. 7, Kabul, Afghanistan; Trade License No. 101016 (Afghanistan) [SDNTK].

2. AVANTI JOYEROS E.U. (f.k.a. ''ORLY OVADIA DE GUBEREK EMPRESA UNIPERSONAL''), Calle 17 No. 68D–52, Bogota, Colombia; Matricula Mercantil No 745957 (Colombia) [SDNTK].

3. CONSTRUCTORA NACIONAL DE PANAMA S.A., Panama City, Panama; RUC #107196–1–379500 (Panama) [SDNTK].

4. GUBEREK GRIMBERG E HIJOS Y CIA. S. EN C., Bogota, Colombia; NIT #8000609604 (Colombia) [SDNTK].

5. MUSHTAQ SHAHEEN CONSTRUCTION AND ROADMAKING COMPANY (a.k.a. MUSHTAQ SHAHEEN LTD), Surai Shahzada, Ground Floor, Shop No. 7, Surai Shahzada, Kabul, Afghanistan; Surai Shahzada, Shop No. 7, Ground Floor, Surai Shahzada, Kabul, Afghanistan; Room No. 7, Sarai Shahzada Mandawi, Kabul District No. 1, Afghanistan; Commercial Registry Number 31225 (Afghanistan) [SDNTK].

Dated: September 29, 2016.

Gregory T. Gatjanis,

Associate Director, Office of Global Targeting, Office of Foreign Assets Control.

[FR Doc. 2016–24184 Filed 10–5–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Proposed Collection; Comment Request

AGENCY: Departmental Offices, Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on this continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before December 5, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to the Department of the Treasury, Office of Financial Stability, ATTN: Nicole Brandon, 1500 Pennsylvania Avenue NW., Washington, DC 20020 or to *Nicole.Brandon@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the Department of the Treasury, Office of Financial Stability, ATTN: Nicole Brandon, 1500 Pennsylvania Avenue NW., Washington, DC 20020; (202) 622–0981;; or *Nicole.Brandon@treasury.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1505–0222.

Title: Troubled Asset Relief Program (TARP)—Capital Purchase Program (CPP) Annual Use of Capital Survey.

Abstract: The Treasury Department is committed to determining the effectiveness of all of the programs of the Office of Financial Stability (OFS). The purpose of the Use of Capital Survey is to obtain insight into the lending, financial intermediation, and capital building activities of all recipients of government investment through CPP and Community Development Capital Initiative (CDCI) funds. The survey is designed to capture representative information of CPP and CDCI fund usage without imposing excessive burdens on institutions.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profits (financial institutions).

Estimated Number of Annual Respondents: 68.

Estimated Hours per Response: 3.

Estimated Total Annual Burden Hours: 204.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. Comments may become a matter of public record. The public is invited to submit comments concerning: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: October 3, 2016.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–24227 Filed 10–5–16; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

October 3, 2016.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before November 7, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8117, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Control Number: 1545–xxxx.

Type of Review: New collection (Request for a new OMB control number).

Title: Form 14693, Application for Reduced Rate of Withholding on Whistleblower Award Payment.

Form: 14693.

Abstract: Form 14693 is used by a claimant who has been notified that they are due to receive a whistleblower award and who wishes to reduce the rate of withholding on the award.

Affected Public: Individuals or households.

Estimated Total Annual Burden Hours: 75.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–24230 Filed 10–5–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0376]

Proposed Information Collection (Agent Orange Registry Code Sheet; VA Form 10–9009) Activity: Comment Request

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Health Administration (VHA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to identify areas for improvement in clinical training programs.

DATES: Written comments and recommendations on the proposed

collection of information should be received on or before December 5, 2016.

ADDRESSES: Submit written comments on the collection of information through the Federal Docket Management System (FDMS) at *www.Regulations.gov;* or to Brian McCarthy, Office of Regulatory and Administrative Affairs, Veterans Health Administration (10B4), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email: *Brian.McCarthy4@va.gov.* Please refer to ''OMB Control No. 2900–0376'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Brian McCarthy at (202) 461–6345.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501—3521), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Titles: Agent Orange Registry Code Sheet, VA Form 10–9009.

OMB Control Number: 2900–0376.

Type of Review: Reinstatement without change of a previously approved collection.

Abstract: VA employees obtain demographic data from existing records. The examining physician, Environmental Health (EH) Coordinator (formerly identified as the Agent Orange coordinator)/or other designated personnel obtain the remainder of the information during the Agent Orange registry physical examination process. The information obtained from the Veteran is entered directly onto an electronic VA Agent Orange Form 10–9009, Agent Orange Registry Worksheet (formerly identified as an Agent Orange Registry Code Sheet), via a secured Web site *http://vaww.registries.aac.va.gov* by VA personnel and transmitted directly to the Environmental Agents Service (EAS) Agent Orange Registry database located at the Austin Information Technology Center (AITC), Austin, TX. Edits are automatically accomplished at the time of entry. The EAS Registries Web site allows you to edit pretty much all the information that has been entered. Some VA facilities will enter the information into the EAS Registries Web site while the Veteran is sitting in front of them. Other facilities will have the Veteran and the examiner complete the Agent Orange Worksheet on paper form, and then later enter the worksheet data into the EAS Registries Web site. VHA Handbook 1302.01, dated 9/5/06 states: ''AOR worksheets and dated follow-up letters must be scanned, or made electronic, and attached to an appropriately titled CPRS progress note.''

The registry provides a mechanism to catalogue prominent symptoms, reproductive health, and diagnoses and to communicate with Agent Orange Veterans. VA keeps Veterans informed on research findings or new compensation policies through periodic newsletters. The voluntary, self-selected nature of this registry makes it valuable for health surveillance; however, it is not designed or intended to be a research tool and therefore, the results cannot be generalized to represent all Agent Orange Veterans.

Affected Public: Individuals or households.

Estimated Annual Burden: 6,667 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: Annually.

Estimated Annual Responses: 20,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Enterprise Records Management Service, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–24156 Filed 10–5–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Research Advisory Committee on Gulf War Veterans' Illnesses; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C., App. 2, that the Research Advisory Committee on Gulf War Veterans' Illnesses will meet on November 7, 2016, in Room 230 at Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC, from 9:00 a.m. until 4:00 p.m. (EST). All sessions will be open to the public, and for interested parties who cannot attend in person, there is a toll-free telephone number (800) 767–1750; access code 56978#.

The purpose of the Committee is to provide advice and make recommendations to the Secretary of Veterans Affairs on proposed research studies, research plans, and research strategies relating to the health consequences of military service in the Southwest Asia theater of operations during the Gulf War in 1990–1991.

The Committee will review VA program activities related to Gulf War Veterans' illnesses, and updates on relevant scientific research published since the last Committee meeting. Presentations will include updates on the VA Gulf War research program, along with presentations describing new areas of research that can be applied to the health problems of Gulf War Veterans. Also, there will be a discussion of Committee business and activities.

The meeting will include time reserved for public comments in the afternoon. A sign-up sheet for 5-minute comments will be available at the meeting. Individuals who wish to address the Committee may submit a 1–2 page summary of their comments for inclusion in the official meeting record. Members of the public may also submit written statements for the Committee's review to Dr. Victor Kalasinsky via email at *victor.kalasinsky@va.gov.*

Because the meeting is being held in a government building, a photo I.D. must be presented at the Guard's Desk as a part of the clearance process. Due to an increase in security protocols, and in order to prevent delays in clearance processing, you should allow an additional 30 minutes before the meeting begins. Any member of the public seeking additional information should contact Dr. Kalasinsky, Designated Federal Officer, at (202) 443–5600.

Dated: October 3, 2016.

LaTonya L. Small,

Advisory Committee Management Officer.

[FR Doc. 2016–24228 Filed 10–5–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0696]

Agency Information Collection (Availability of Educational Licensing, and Certification Records) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before November 7, 2016.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0696'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0696.''

SUPPLEMENTARY INFORMATION:

Title: Availability of Educational Licensing, and Certification Records.

OMB Control Number: 2900–0696.

Type of Review: Revision of a currently approved collection.

Abstract: Educational institutions (including licensing and certification organizations) with approved courses or tests must make records available to government representatives. These records are used to insure that payment of benefits under the education programs VA administers have been made correctly.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at Vol. 81, No. 141, Friday, July 22, 2016,

Affected Public: Educational institutions.

Estimated Annual Burden: 11,400 hours.

Estimated Average Burden per Respondent: 2 hours.

Frequency of Response: Annually.

Estimated Number of Respondents: 5,700 respondents.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–24162 Filed 10–5–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0021]

Agency Information Collection: VA Loan Electronic Reporting Interface (VALERI) System; Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before November 7, 2016.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0021'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0021.''

SUPPLEMENTARY INFORMATION:

Title: VA Loan Electronic Reporting Interface (VALERI) System.

OMB Control Number: 2900–0021.

Type of Review: Revision of a currently approved collection.

Abstract: VA conducted an in-depth internal review of the entire Loan Administration process. As a result of this review, VA changed previous procedures which include: collections of information and record retention related to the increased authority of servicers to implement loss-mitigation options; processing of loan modifications; increased information reporting requirements for servicers; elimination of currently-required Notices of Intention to Foreclose; reduction in the amount of documentation provided to VA incident to refunding loans; significant reduction in reporting and recordkeeping burdens pertaining to legal proceedings, including bankruptcies and foreclosures; changes in the way servicers are permitted to file an election to convey properties to VA; provisions permitting claims to be filed electronically instead of paper submission; authorizing certain servicers to process releases of liability and partial releases; and permitting certain servicers the authority to process liquidation appraisals instead of VA and its appraisers.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 81 FR 47857 on July 22, 2016.

Affected Public: Individuals or households.

Estimated Annual Burden: 70 hours.

Estimated Average Burden per Respondent: 1 second.

Frequency of Response: One-time.

Estimated Number of Respondents: 260.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–24158 Filed 10–5–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0703]

Agency Information Collection (Dependent's Educational Assistance (DEA)) OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before November 7, 2016.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0703'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0703.''

SUPPLEMENTARY INFORMATION:

Title: DEPENDENT'S EDUCATIONAL ASSISTANCE (DEA).

OMB Control Number: 2900–0703.

Type of Review: Revision of a currently approved collection.

Abstract: For the VA Form 22–0703, VA will use the information collected to determine when to begin their payment. It is mandatory VA notify the dependent child under 38 U.S.C. 3512(a) the opportunity to make an election. Under 38 U.S.C. 3512(b) it is not mandatory VA provide spouses the opportunity to make an election, but they may also elect a begin date. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 81 FR 15985 on Wednesday, July 6, 2016.

Affected Public: Individuals or Households.

Estimated Annual Burden: 96 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One-time during benefit period.

Estimated Number of Respondents: 384 respondents.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–24155 Filed 10–5–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0798]

Proposed Information Collection (Beneficiary Travel Mileage Reimbursement Application Form, VA Form 10–3542) Activity: OMB Review

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Health Administration (VHA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before November 7, 2016.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0798'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0798.''

SUPPLEMENTARY INFORMATION:

Title: Beneficiary Travel Mileage Reimbursement Application Form.

OMB Control Number: 2900–0798.

Type of Review: Extension of a Currently Approved Collection.

Abstract: The information collection is for beneficiaries to apply for the BT mileage reimbursement benefit. VHA determines the identity of the claimant, the dates and length of the trip being claimed based on addresses of starting and ending points, and whether expenses other than mileage are being claimed. The claimant is required to sign the form. The form is used only when the claimant chooses not to apply verbally and is provided for their convenience. Once the information is obtained it is entered into a software program that calculates the mileage and resulting reimbursement. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at Vol. 81, No. 129, Friday, July 6, 2016

Affected Public: Individuals or households.

Estimated Annual Burden: 580,000 hours.

Estimated Average Burden per Respondent: 3 minutes.

Frequency of Response: 8 per year.

Estimated Number of Respondents: 1,450,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–24159 Filed 10–5–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0600]

Agency Information Collection: (Reconsideration of Denied Claims) Activity: Comment Request

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Health Administration (VHA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and

Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before November 7, 2016.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0600'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0600.''

SUPPLEMENTARY INFORMATION:

This request does not include a form. This informal process only requires submission of a written request for reconsideration denial of healthcare benefits.

OMB Control Number: 2900–0600.

Type of Review: Revision of a currently approved collection.

Abstracts: Provisions for this data collection are included in 38 CFR 17.133. This informal process provides for submission of a written request for reconsideration denial of healthcare benefits. The request contains the reason the claimant believes the decision is erroneous and allows submission of new and relevant information. This process reduces both formal appeals and allows decision making to be more responsive to Veterans using the VA healthcare system. The **Federal Register** Notice with a 60-day period soliciting comments on this collection of information was published at Vol. 81, No. 120, Wednesday, June 22, 2016.

Affected Public: Individuals or households.

Estimated Annual Burden: 50,826 burden hours.

Estimated Average Burden per Respondent: 30 minutes per response.

Frequency of Response: Annually.

Estimated Annual Responses: 101,652 respondents.

By direction of the Secretary:

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–24153 Filed 10–5–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0365]

Proposed Information Collection (Request for Disinterment) Activity: Comment Request

AGENCY: National Cemetery Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The National Cemetery Administration (NCA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection and allow 60 days for public comment in response to the notice. This notice solicits comments on the information needed to determine a claimant entitlement to disinter the remains of a loved one from or within a national cemetery.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before December 5, 2016.

ADDRESSES: Submit written comments on the collection of information through the Federal Docket Management System (FDMS) at *www.Regulations.gov;* or to Willie Lewis, National Cemetery Administration (40D), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420; or email: *Willie.Lewis@va.gov.* Please refer to ''OMB Control No. 2900–0365'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Willie Lewis at (202) 461–4242 or FAX (202) 501–2240.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, NCA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of NCA's functions, including whether the information will have practical utility; (2) the accuracy of NCA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Request for Disinterment, VA Form 40–4970.

OMB Control Number: 2900–0365.

Type of Review: Extension of a currently approved collection.

Abstract: Claimants complete VA Form 40–4970 to request removal of remains from a national cemetery for interment at another location. Interments made in national cemeteries are permanent and final. All immediate family members of the decedent, including the person who initiated the interment, (whether or not he/she is a member of the immediate family) must provide a written consent before disinterment is granted. VA will accept an order from a court of local jurisdiction in lieu of VA Form 40–4970.

Affected Public: Individuals or Households.

Estimated Annual Burden: 185.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 1106.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–24161 Filed 10–5–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0568]

Proposed Information Collection (Submission of School Catalog to the State Approving Agency) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed from accredited and nonaccredited educational institutions.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before December 5, 2016.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0568'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501—21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Submission of School Catalog to the State Approving Agency.

OMB Control Number: 2900–0568.

Type of Review: Revision of a currently approved collection.

Abstract: Accredited and nonaccredited educational institutions, with the exception of elementary and secondary schools, must submit copies of their catalog to the State approving agency when applying for approval of a new course. State approving agencies use the catalog to determine what courses can be approved for VA training. VA pays educational assistance to veterans, persons on active duty or reservists, and eligible persons pursuing an approved program of education. Educational assistance is not payable when claimants pursue unapproved courses.

Affected Public: Not-for-profit institutions.

Estimated Annual Burden: 2,487 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 9,948.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–24160 Filed 10–5–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0698]

Agency Information Collection (Application for Educational Assistance to Supplement Tuition Assistance) OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before November 7, 2016.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0698'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0698.''

SUPPLEMENTARY INFORMATION:

Title: Application for Educational Assistance To Supplement Tuition Assistance, 38 CFR 21.1030(c), 21.7140(c)(5).

OMB Control Number: 2900–0698.

Type of Review: Revision of a currently approved collection.

Abstract: Claimants who wish to receive educational assistance administered by VA to supplement tuition assistance administered by the Department of Defense must apply through VA. VA will use the data collected to determine the claimant's eligibility to receive educational assistance to supplement the tuition assistance he or she received and the amount payable.

The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 81 FR 17341 on July 22, 2016.

Affected Public: Individuals or Households.

Estimated Annual Burden: 1,600 hours.

Estimated Average Burden per Respondent: 12 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 8,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–24154 Filed 10–5–16; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0011]

Agency Information Collection: Application for Reinstatement—Insurance Lapsed More Than 6 Months (29–352) and Application for Reinstatement—Non Medical Comparative Health Statement (29–353)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

ACTIVITY: Under OMB Review.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before November 7, 2016.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0011'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0011.''

SUPPLEMENTARY INFORMATION:

Title: Application for Reinstatement—Insurance Lapsed More Than 6 Months (29–352).

Application for Reinstatement—Non Medical Comparative Health Statement (29–353).

OMB Control Number: 2900–0011.

Type of Review: Revision of a currently approved collection.

Abstract: These forms are used by veterans who are requesting a reinstatement of their lapsed life insurance policies. The information requested on the forms is required by law, 38 U.S.C. Sections 6.79 and 8.22.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at Vol. 81, No. 170, Thursday, September 1, 2016.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,125 hours.

Estimated Average Burden per Respondent: 22.5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 3000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–24164 Filed 10–5–16; 8:45 am]

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 314 and 320

Abbreviated New Drug Applications and 505(b)(2) Applications; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 320

[Docket No. FDA–2011–N–0830]

RIN 0910–AF97

Abbreviated New Drug Applications and 505(b)(2) Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to implement Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which amended provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that govern the approval of 505(b)(2) applications and abbreviated new drug applications (ANDAs). This final rule implements portions of Title XI of the MMA that pertain to provision of notice to each patent owner and the new drug application (NDA) holder of certain patent certifications made by applicants submitting 505(b)(2) applications or ANDAs; the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved; submission of amendments and supplements to 505(b)(2) applications and ANDAs; and the types of bioavailability and bioequivalence data that can be used to support these applications. This final rule also amends certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act.

DATES: This rule is effective December 5, 2016.

ADDRESSES: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Janice L. Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6268, Silver Spring, MD 20993–0002, 301–796–3601.

With regard to the information collection: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov*.

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I. Executive Summary

I.A. Purpose of the Final Rule

This rule implements portions of Title XI of the MMA and revises and clarifies FDA regulations relating to 505(b)(2) applications and ANDAs in a manner intended to reduce unnecessary litigation, reduce delays in the approval of 505(b)(2) applications and ANDAs that are otherwise ready to be approved, and provide business certainty to both brand name and generic drug manufacturers.

Title XI of the MMA addressed two key concerns identified in a Federal Trade Commission (FTC) report on anticompetitive strategies that may delay access to generic drugs by: (1) Limiting the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved and (2) establishing conditions under which a first applicant would forfeit the 180-day exclusivity period such that approval of subsequent ANDAs would no longer be blocked. FDA has been implementing the MMA directly from the statute since its enactment. Based on this experience, FDA is amending its regulations to implement portions of the MMA that pertain to 30-month stays and other matters not related to forfeiture of 180-day exclusivity.

FDA is amending its regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act, and to clarify and update these regulations based on recent court decisions and our practical experience implementing provisions related to the approval of 505(b)(2) applications and ANDAs. For example, we are clarifying requirements for the NDA holder's description of the specific approved method of use claimed by the patent (the ''use code'') required for publication in FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) to address overbroad or ambiguous use codes that may delay approval of generic drugs. This clarification is intended to facilitate FDA's implementation of the statutory provisions that permit 505(b)(2) and ANDA applicants to omit (''carve out'') protected conditions of use from labeling and obtain approval for conditions of use that are not covered by unexpired patents or exclusivity. We also are revising the regulations to codify the types of court decisions and other actions that will terminate a 30-month stay of approval on a 505(b)(2) application or ANDA. Finally, we are updating the regulations to codify FDA's current practice and policy and thereby promote transparency.

I.B. Summary of the Major Provisions of the Final Rule

I.B.1. Submission of Patent Information

The rule revises and streamlines requirements related to submission of patent information on: (1) Patents that claim the drug substance and/or drug product and meet the requirements for patent listing on that basis; (2) drug substance patents that claim only a polymorph of the active ingredient; and (3) certain NDA supplements.

We are codifying our longstanding requirement that the NDA holder's description of the patented method of use required for publication in the Orange Book must contain adequate information to assist FDA and 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval. To address overbroad or ambiguous use codes, we are expressly requiring that if the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, the NDA holder's use code must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product.

I.B.2. Timing of Submission of Patent Information

We are expressly describing our current practice with respect to listing patent information that has not been submitted to FDA within 30 days after patent issuance. Although we list untimely filed patents pursuant to section 505(c)(2) of the FD&C Act (21 U.S.C. 355(c)(2)), we generally do not require an applicant with a pending 505(b)(2) application or ANDA to provide a patent certification to the untimely filed patent. Thus, the untimely filed patent will neither delay approval of a pending 505(b)(2) application or ANDA until patent expiration nor necessitate a carve-out of information related to a patented method of use.

We are expanding the category of untimely filed patent information to include certain amendments to the NDA holder's description of the approved method(s) of use claimed by the patent, if such changes are not submitted: (1) Within 30 days of patent issuance; (2) within 30 days of approval of a corresponding change to product labeling; or (3) within 30 days of a decision by the U.S. Patent and Trademark Office (USPTO) or a Federal court that is specific to the patent and alters the construction of a method-of-use claim(s) of the patent. This revision to our regulations is intended to reduce delays in approval related to overbroad or ambiguous patent use codes.

In addition, we are establishing that the submission date of patent information provided by an NDA holder after approval will be the earlier of the date on which Form FDA 3542 is date-stamped by the Central Document Room or officially received by FDA in an electronic format. These revisions are intended to facilitate prompt listing in the Orange Book and to remove any ambiguity about the date of submission in light of the implications of untimely filed patent information for the patent certification obligations of 505(b)(2) and ANDA applicants that rely upon the listed drug.

I.B.3. Correction or Change of Patent Information

We are clarifying and improving the procedures that govern challenges to the accuracy or relevance of the NDA holder's submission of patent information to the Agency. These procedures allow a person (including a 505(b)(2) or ANDA applicant) to request, for example, that an NDA holder confirm that a previously submitted use code complies with current requirements. We are establishing a 30-day timeframe in which the NDA holder will be required to substantively respond to the patent listing dispute and verify the accuracy and completeness of the response. We intend to take an incremental approach and evaluate whether FDA's revisions to the regulations on submission of method-of-use patent information and patent listing dispute procedures adequately address the problem of overbroad and ambiguous use codes before we determine whether a process to review a proposed labeling carve-out with deference to the 505(b)(2) and/or ANDA applicant(s)' interpretation of the scope of the patent is also needed.

In addition, we are expressly requiring the correction or change of patent information by the NDA holder if: (1) The patent or patent claim no longer meets the statutory requirements for listing; (2) the NDA holder is required by court order to amend patent information or withdraw a patent from the list; or (3) the term of a listed patent is extended under patent term restoration provisions. These revisions facilitate implementation of the MMA provision related to patent withdrawal and efficient enforcement of the FD&C Act.

I.B.4. Notice of Paragraph IV Certification—Timing

We are revising our regulations to clearly delineate the two limitations on the timeframe within which notice of a paragraph IV certification can be provided to the NDA holder and each patent owner: (1) The date before which notice may not be given (reflecting FDA's longstanding practice regarding premature notice) and (2) the date, established by MMA, by which notice must be given to be considered timely.

For an original application, a 505(b)(2) applicant must send notice of a paragraph IV certification on or after the date on which the 505(b)(2) application is filed and an ANDA applicant must send notice of a paragraph IV certification on or after the date on which it receives a ''paragraph IV acknowledgment letter'' from FDA stating that the application is sufficiently complete to permit a substantive review. Both 505(b)(2) and ANDA applicants must send notice of a paragraph IV certification not later than 20 days after the date of the ''postmark'' (as defined in this final rule) on the paragraph IV acknowledgment letter.

For an amendment or supplement, an applicant must send notice of a paragraph IV certification contained in an amendment to a 505(b)(2) application (that has been filed) or ANDA (that has been received for substantive review) or in a supplement to an approved application at the same time that the amendment or supplement is submitted to FDA.

We are establishing a date (the first working day after the day the patent is published in the Orange Book) before which an ANDA applicant cannot send valid notice of a paragraph IV certification to a newly listed patent. Notice of a paragraph IV certification that has been sent prematurely is invalid, and will not be considered to comply with the FD&C Act's notice requirement. This approach is intended to promote equity among ANDA applicants seeking eligibility for 180-day exclusivity and to reduce the burden on industry and FDA associated with serial submissions and multiple notices of paragraph IV certifications related to a newly issued patent.

I.B.5. Notice of Paragraph IV Certification—Content and Methods

We are revising the content of notice of a paragraph IV certification to incorporate requirements added by the MMA and to support the efficient enforcement of our regulations. We are also expanding the acceptable methods of sending notice of a paragraph IV

certification beyond registered or certified mail to include ''designated delivery services.'' This reduces the burden on 505(b)(2) and ANDA applicants who currently must submit requests to the Agency to send notice by common alternate delivery methods.

I.B.6. Amended Patent Certifications

We are clarifying the requirements for a 505(b)(2) or ANDA applicant to amend a paragraph IV certification after a judicial finding of patent infringement to reflect statutory changes made by the MMA. We are also clarifying the circumstances and timeframe in which a 505(b)(2) or ANDA applicant must submit an amended patent certification after an NDA holder has withdrawn a patent and requested removal of the patent from the Orange Book. The rule codifies our current practice of not removing a withdrawn patent from the list until FDA has determined that no first applicant is eligible for 180-day exclusivity or the 180-day exclusivity period based on that patent has expired or has been extinguished, and exempting 505(b)(2) applicants from providing or maintaining a certification to withdrawn patents. In addition, the rule expressly codifies the current requirement for a 505(b)(2) or ANDA applicant to submit a patent certification to a timely filed, newly issued patent that claims the listed drug or an approved method of using such drug.

I.B.7. Patent Certification Requirements for Amendments

We are clarifying and augmenting the patent certification requirements for amendments to 505(b)(2) applications and ANDAs to ensure that certain types of changes to the drug product are accompanied by an appropriate patent certification (or recertification) or statement. An appropriate patent certification (or recertification) or statement is required to accompany an amendment to add a new indication or other condition of use, to add a new strength, to make other-than-minor changes in product formulation, or to change the physical form or crystalline structure of the active ingredient. The regulations continue to require that a patent certification be amended if, at any time before approval, the applicant learns that the previously submitted patent certification or statement is no longer accurate.

I.B.8. Limitation on Submission of Certain Amendments and Supplements to a 505(b)(2) Application or ANDA

We are codifying our current interpretation of the MMA's prohibition on submitting an amendment or a supplement to seek approval of: (1) ''[A] drug that is a different drug'' than the drug identified in the original 505(b)(2) application; or (2) ''a drug referring to a different listed drug'' than the drug cited as the basis for ANDA submission. We are implementing these parallel restrictions on submission of certain types of changes in an amendment or a supplement to a 505(b)(2) application or ANDA in a manner that is consistent with the statutory text and preserves a meaningful opportunity for a single 30-month stay.

I.B.9. 505(b)(2) Applications

We are requiring a 505(b)(2) applicant to identify one pharmaceutically equivalent drug product approved in an NDA, if one or more is approved before the original 505(b)(2) application is submitted, as a listed drug relied upon, and comply with applicable regulatory requirements. This is intended to help ensure that the 505(b)(2) pathway is not used to circumvent the statutory patent certification obligations that would have applied if the proposed product could have been approved in an ANDA.

I.B.10. Date of Approval of a 505(b)(2) Application or ANDA

The rule describes, in a more comprehensive manner, the timing of approval of a 505(b)(2) application or ANDA based on the patent certification(s) or statement(s) submitted by the 505(b)(2) or ANDA applicant. We are revising the regulations to reflect the MMA's limitation on multiple 30-month stays of approval of a 505(b)(2) application or an ANDA containing a paragraph IV certification to certain patents.

We are clarifying that the statutory 30-month stay begins on the later of the date of receipt of notice of paragraph IV certification by any owner of the listed patent or by the NDA holder (or its representative(s)). This revision codifies our current practice and provides an efficient means of ensuring that each patent owner or NDA holder receives the full statutory 30-month stay.

We are codifying the MMA's amendments that clarify the type of Federal district and appellate court decisions in patent litigation that will terminate a 30-month stay and lead to approval of a 505(b)(2) application or ANDA that is otherwise eligible for approval. We are also addressing other scenarios in which a 30-month stay may be terminated, including written consent to approval by the patent owner or exclusive patent licensee, a court order terminating the stay, or a court order of dismissal without a finding of infringement in each pending suit for patent infringement brought within 45 days of receipt of the notice of paragraph IV certification. These clarifications are intended to avoid unnecessary delays in approval of 505(b)(2) applications and ANDAs while upholding the statutory purpose of the stay (*i.e.,* to allow time for patent infringement claims to be litigated prior to approval of the potentially infringing product).

I.B.11. Notification of Commercial Marketing

We are updating the regulations to reflect the MMA provisions that modify the types of events that can trigger the start of the 180-day exclusivity period. A first applicant is required to submit correspondence to its ANDA notifying FDA within 30 days of the date of first commercial marketing of the drug product. If a first applicant does not notify FDA within this timeframe, we are deeming the date of first commercial marketing to be the date of the drug product's approval. This may have the effect of shortening the 180-day exclusivity period in a similar manner to the current regulatory consequence for failure to provide ''prompt'' notice of first commercial marketing.

I.B.12. Notification of Court Actions or Written Consent to Approval

We are expanding the scope of documentation that an applicant must submit to FDA regarding patent-related court actions and written consent to approval to ensure that FDA is promptly advised of information that may affect the timing of approval of a 505(b)(2) application or ANDA.

I.C. Legal Authority

Title XI of the MMA and sections 505, 505A, 505E, and 527 of the FD&C Act (21 U.S.C. 355, 355a, 355f, and 360cc), in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)), serve as our principal legal authority for this rule.

I.D. Costs and Benefits

Many provisions of this final rule codify current practice, but some elements will lead to changes that generate additional benefits and costs. The table summarizes the benefits and costs of this final rule. The estimated annualized monetized benefits of this final rule are $215,247 at a 3 percent or 7 percent discount rate, while the estimated annualized monetized costs are $266,947 at a 3 percent discount rate and $275,925 at a 7 percent discount rate. We have also identified, but are

unable to quantify, additional impacts from changes to submitted patent information.

SUMMARY OF BENEFITS AND COSTS

	Benefits	Costs
One-time (Year 1) Cost for Reading the Rule	NA	$466,450
Annually Recurring Compliance Costs or Savings (Years 1–10)	$215,247	213,858
Present Value at 3 Percent	1,836,098	2,277,116
Present Value at 7 Percent	1,511,803	1,937,983
Annualized Value at 3 Percent	215,247	266,947
Annualized Value at 7 Percent	215,247	275,925

NA = Not Applicable.

II. Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation	What it means
ANDA	Abbreviated New Drug Application.
CDER	Center for Drug Evaluation and Research.
CFR	Code of Federal Regulations.
CSA	Controlled Substances Act.
ESG	Electronic Submissions Gateway.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	U.S. Food and Drug Administration.
FDASIA	Food and Drug Administration Safety and Innovation Act.
FOIA	Freedom of Information Act.
FR	Federal Register.
FTC	U.S. Federal Trade Commission.
GAIN	Generating Antibiotic Incentives Now.
GDUFA	Generic Drug User Fee Amendments of 2012.
IRTNMTA	Improving Regulatory Transparency for New Medical Therapies Act.
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
NDA	New Drug Application.
OGD	Office of Generic Drugs (in FDA's Center for Drug Evaluation and Research).
OMB	U.S. Office of Management and Budget.
OND	Office of New Drugs (in FDA's Center for Drug Evaluation and Research).
Orange Book	FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations''.
OTC	Over-the-counter.
RLD	Reference Listed Drug.
U.S.	United States.
U.S.C.	United States Code.
USPS	United States Postal Service.
USPTO	U.S. Patent and Trademark Office.

III. Background

The 505(b)(2) application and ANDA approval pathways were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (Hatch-Waxman Amendments). The Hatch-Waxman Amendments reflect Congress's efforts to balance the need to ''make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962'' with new incentives for drug development in the form of marketing exclusivity and patent term extensions (see H. Rept. 98–857, part 1, at 14–15 (1984), reprinted in 1984 U.S. Code Congressional and Administrative News 2647 at 2647–2648).

A 505(b)(2) application is an NDA that contains full reports of investigations of safety and effectiveness, where at least some of the information relied upon by the applicant for approval of the NDA comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (*e.g.,* published literature or the Agency's finding of safety and/or effectiveness for one or more listed drugs) (see section 505(b)(2) of the FD&C Act; compare section 505(b)(1) of the FD&C Act for ''stand-alone'' NDAs).

An ANDA contains information to show that the proposed product is the same as a previously approved drug (the reference listed drug or RLD) with respect to active ingredient, conditions of use, dosage form, route of administration, strength, and (with certain permissible differences) labeling, among other characteristics. An ANDA applicant also must demonstrate that its proposed drug product is bioequivalent to the RLD (see section 505(j) of the FD&C Act; compare section 505(j)(2)(C) for ''petitioned ANDAs''). An applicant that can meet the requirements for approval under section 505(j) of the FD&C Act may rely upon the Agency's finding of safety and effectiveness for the RLD and need not repeat the extensive nonclinical and clinical investigations required for approval of a ''stand-alone'' NDA submitted under section 505(b)(1) of the FD&C Act.

The timing of approval for a 505(b)(2) application and an ANDA (including a petitioned ANDA) is subject to certain patent and marketing exclusivity protections. An NDA applicant is required to submit information on any patent that claims the drug that is the subject of the NDA or that claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug (section 505(b)(1) and (c)(2) of the FD&C Act). Upon approval of an NDA under section 505(c) of the FD&C Act, we publish certain patent information provided by the NDA holder in the Orange Book, available electronically on FDA's Web site at *http://www.fda.gov/cder*.

A 505(b)(2) application and ANDA must include an appropriate patent certification or statement for each patent that claims the listed drug(s) relied upon or RLD, respectively, or a method of using such drug and for which information is required to be filed under section 505(b) or 505(c) of the FD&C Act. The 505(b)(2) or ANDA applicant must submit one or more of the following certifications or statements:

- That such patent information has not been filed (a paragraph I certification);
- that such patent has expired (a paragraph II certification);
- the date on which such patent will expire (a paragraph III certification);
- that such patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the 505(b)(2) application or ANDA is submitted (a paragraph IV certification);
- that there are no patents that claim the listed drug(s) or that claim a use of such drug (a ''no relevant patents'' statement, which is submitted instead of a patent certification); or
- that a method-of-use patent does not claim a use for which the 505(b)(2) or ANDA applicant is seeking approval (a 505(b)(2)(B) or (j)(2)(A)(viii) statement).

An applicant that submits a paragraph IV certification is required to give notice of the paragraph IV certification to the NDA holder for the listed drug(s) relied upon or RLD and each owner of the patent that is the subject of the certification. Notice of a paragraph IV

certification subjects the 505(b)(2) or ANDA applicant to the risk that it will be sued for patent infringement. If the NDA holder or patent owner initiates a patent infringement action within 45 days after receiving notice of the paragraph IV certification, there generally will be a statutory 30-month stay of approval of the 505(b)(2) application or ANDA while the patent infringement litigation is pending (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act).

ANDA applicants have a statutory incentive to challenge listed patents that may be invalid, unenforceable, or not infringed by the drug product described in the ANDA. The first applicant to submit a substantially complete ANDA that contains, and for which the applicant lawfully maintains, a paragraph IV certification may be eligible for a 180-day period of marketing exclusivity (180-day exclusivity) during which approval of subsequent ANDAs containing a paragraph IV certification to a listed patent for the same drug product will not be granted (see section 505(j)(5)(B)(iv) of the FD&C Act).

III.A. History of This Rulemaking

On December 8, 2003, the MMA (Pub. L. 108–173) was signed into law. Title XI of the MMA significantly amended provisions of the FD&C Act that govern the approval of 505(b)(2) applications and ANDAs. Title XI of the MMA addressed two key concerns identified in an FTC report on ''Generic Drug Entry Prior to Patent Expiration: An FTC Study'' (July 2002) (Ref. 1) by limiting the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved (30-month stays) and by establishing conditions under which a first applicant would forfeit the 180-day exclusivity period such that approval of subsequent ANDAs would no longer be blocked.

Section 1101 of the MMA provides that a 30-month stay of approval of a 505(b)(2) application or ANDA is available only if patent infringement litigation was initiated within the 45-day period after receipt of notice of a paragraph IV certification for a patent that had been submitted to FDA before the date of submission of the 505(b)(2) application or ANDA (excluding an amendment or supplement to the 505(b)(2) application or ANDA). The resulting incentive for an applicant to change the listed drug relied upon through an amendment of or a supplement to a 505(b)(2) application or ANDA is addressed by the MMA's prohibition of the submission of certain types of changes (including those requiring reference to a different listed drug) in an amendment of or supplement to a 505(b)(2) application or ANDA. In addition, section 1101 of the MMA amended the FD&C Act to specify certain types of court actions that will terminate a 30-month stay of approval.

Section 1101 of the MMA also created new requirements for 505(b)(2) and ANDA applicants sending notice of a paragraph IV certification, including changes to the timing and contents of such notice. In addition, the MMA established conditions under which a 505(b)(2) or ANDA applicant may bring a declaratory judgment action to obtain ''patent certainty'' (*i.e.,* obtain a judicial determination of non-infringement, invalidity, or unenforceability) with respect to a listed patent for which it has given notice of a paragraph IV certification but has not been sued by the NDA holder or patent owner(s) within the statutory timeframe. If a patent infringement action is initiated against the 505(b)(2) or ANDA applicant, the MMA provides that the applicant may assert a counterclaim seeking an order requiring a correction or deletion of the patent information submitted to FDA for listing by the NDA holder.

Section 1102 of the MMA altered the conditions under which a 180-day period of marketing exclusivity attaches by requiring, among other things, that a first applicant lawfully maintain the paragraph IV certification contained in its submission of a substantially complete ANDA. In addition, section 1102 of the MMA established conditions under which a first applicant would forfeit the 180-day exclusivity period.

Section 1103 of the MMA clarified the types of bioavailability and bioequivalence data that can be used to support a 505(b)(2) application or ANDA for a drug that is not intended to be absorbed into the bloodstream.

On March 3, 2004, we published a notice in the **Federal Register** entitled ''Generic Drug Issues; Request for Comments'' (69 FR 9982), which invited public comment to further identify issues related to the MMA provisions regarding 30-month stays, 180-day exclusivity, and bioavailability and bioequivalence, along with any suggestions for how to resolve those issues.

On February 6, 2015, we published a proposed rule to implement portions of the MMA that pertain to 30-month stays and other matters not related to forfeiture of 180-day exclusivity, and make our regulations governing 505(b)(2) applications and ANDAs consistent with the MMA's amendments to the FD&C Act (80 FR 6802, February 6, 2015; see also ''Abbreviated New Drug Applications and 505(b)(2) Applications; Correction,'' 80 FR 13289, March 13, 2015). In addition, the proposed rule would amend the regulations in parts 314 and 320 (21 CFR parts 314 and 320) regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act, and to clarify and update these regulations based on our practical experience implementing the provisions related to approval of 505(b)(2) applications and ANDAs. We will determine whether additional rulemaking related to 180-day exclusivity is necessary in the future.

FDA provided 120 days for public comment on the proposed rule, including a 30-day extension of the original comment period (see ''Abbreviated New Drug Applications and 505(b)(2) Applications; Extension of Comment Period,'' 80 FR 22953, April 24, 2015). We received 13 comment letters on the proposed rule by the close of the comment period, each containing 1 or more comments on 1 or more issues. We received comments from pharmaceutical industry associations, brand and generic drug manufacturers, law firms, and a law student. Based on the comments received, FDA is finalizing the proposed rule with certain revisions and technical amendments.

III.B. General Overview of the Final Rule

This final rule implements portions of Title XI of the MMA and revises and clarifies FDA regulations relating to 505(b)(2) applications and ANDAs. The final rule reflects our consideration of comments on the proposed rule, recent court decisions, and legislative enactments, and incorporates several clarifying revisions and technical amendments. Table 1 summarizes the substantive changes from the proposed rule to the final rule.

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Table 1.--Highlights of Substantive Changes From the Proposed Rule to the Final Rule

21 CFR Section in Final Rule	Description of Change From Proposed Rule See comment or section of this document (identified in parentheses) for more detailed information regarding the change.
314.3	*Definitions (§ 314.3(b))* • Revises the definition of "505(b)(2) application" to clarify that it is an NDA for which "at least some of" the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (see section V.P.3). • Revises the definition of "acknowledgment letter" to delete the reference to 505(b)(2) applications and limit the applicability of this term to ANDAs (see section V.A.1). • Revises the definition of "commercial marketing" to clarify that it includes the introduction or delivery for introduction into interstate commerce of the reference listed drug by the ANDA applicant (see section V.A.2). • Revises the definition of "date of approval" to incorporate section 505(x) of the FD&C Act (see section V.A.3). • Revises the definition of "listed drug" to clarify that a drug product is deemed to be a listed drug on the "date of approval" of the NDA or ANDA (see section V.A.3). • Revises the definition of "substantially complete application" to describe an ANDA that on its face is sufficiently complete to permit a substantive review and clarify that "sufficiently complete" means that the ANDA contains all the information required under section 505(j)(2)(A) of the FD&C Act and does not contain a deficiency described in § 314.101(d) and (e) (see section V.A.5). • Revises the definition of "tentative approval" to include a notification that an NDA or ANDA otherwise meets the requirements for approval under the FD&C Act but cannot be approved because there is a period of exclusivity under section 505E of the FD&C Act (see section V.A.7).
314.50	*Patents claiming drug substance, drug product, or method of use (§ 314.50(i)(1)(i)(C))* • Clarifies that the requirement for a 505(b)(2) applicant to provide an appropriate patent certification or statement for each patent listed in the Orange Book for a pharmaceutically equivalent drug product applies to one such pharmaceutically equivalent drug product approved in an NDA before the date of submission of the original 505(b)(2) application and not a resubmission or a supplement (see section V.H). *Method-of-use patent (§ 314.50(i)(1)(iii)(A))* • Clarifies that a 505(b)(2) applicant may submit a statement under section 505(b)(2)(B) of the FD&C Act if the applicant is not seeking approval for "an" indication or other condition of use claimed by a method-of-use patent rather than "any" indications or other conditions of use claimed by the method-of-use patent (see section V.C.1). *Untimely filing of patent information (§ 314.50(i)(4))* • Provides that an amendment to the description of the approved method(s) of use claimed by the patent will not be considered untimely filing of patent information if the amendment is submitted within 30 days of a decision by the USPTO or a Federal court that is specific to the patent and alters the construction of a method-of-use claim(s) of the patent, and the amendment contains a copy of the decision (see section V.B.2.b).

Table 1.--Highlights of Substantive Changes From the Proposed Rule to the Final Rule--Continued

21 CFR Section in Final Rule	Description of Change From Proposed Rule See comment or section of this document (identified in parentheses) for more detailed information regarding the change.
314.52	*Sending the notice of paragraph IV certification (§ 314.52(b))* • Requires that a 505(b)(2) applicant send notice of a paragraph IV certification on or after the date of filing described in § 314.101(a)(2) or (3), but not later than 20 days after the date of the postmark on the "paragraph IV acknowledgment letter" (see section V.D.1.a). • Removes the requirement for a 505(b)(2) applicant to submit an amendment at the time it sends notice of a paragraph IV certification and permits submission of a single amendment that contains all required information within 30 days of the date on which the last notice is received (see section V.D.3.b). *Content of a notice of paragraph IV certification (§ 314.52(c))* • Omits the proposed requirement that notice of a paragraph IV certification must contain a statement that the 505(b)(2) applicant has received the paragraph IV acknowledgment letter (see section V.D.1.a). *Amendment or supplement to a 505(b)(2) application (§ 314.52(d))* • Requires that after the date of filing of a 505(b)(2) application, the applicant must send notice of a paragraph IV certification included in an amendment or supplement at the same time that the amendment or supplement is submitted to FDA (see section V.D.1.b).
314.53	*General requirements and Reporting Requirements (§ 314.53(b)(1) and (c)(2))* • Clarifies that if the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, the NDA holder's use code must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product (see section V.B.1.c). • Clarifies that the NDA holder submitting information on the method-of-use patent must identify with specificity the section(s) and subsection(s) of the approved labeling that describes the method(s) of use claimed by the patent submitted (see section V.B.1.c). *Other Reporting Requirements (§ 314.53(c)(2))* • Omits the proposed requirement for an NDA holder to include information on whether a patent is a reissued patent of a patent previously submitted for listing (see section V.B.1.e). • Maintains the current requirement for an NDA holder to include information on whether the patent has been submitted previously for the NDA (see section V.B.1.d). • Adds the requirement for an NDA holder to identify, for a patent that has been submitted previously for listing, all change(s) from the previously submitted patent information and specify whether the change is related to the patent or related to an FDA action (see section V.B.2.b). *Supplements (§ 314.53(d)(2))* • Omits the proposal to require an NDA holder to submit a statement with an NDA supplement if the NDA holder is not required to resubmit patent information pursuant to § 314.53(d)(2)(ii)(A) (see section V.B.2.a).

Table 1.–Highlights of Substantive Changes From the Proposed Rule to the Final Rule–Continued

21 CFR Section in Final Rule	Description of Change From Proposed Rule See comment or section of this document (identified in parentheses) for more detailed information regarding the change.
314.53 (continued)	*Where to send submissions of Forms FDA 3542a and 3542 (§ 314.53(d)(4))* • Designates the CDER Central Document Room, rather than the OGD Document Room, as the official repository for submission of Form FDA 3542 and clarifies that Form FDA 3542 can be submitted electronically (see section V.B.2.c). *Submission date of patent information (§ 314.53(d)(5))* • Establishes that the submission date of patent information is the earlier of the date on which Form FDA 3542 is date-stamped by the CDER Central Document Room or officially received by FDA in an electronic format submission that complies with § 314.50(l)(5) (see section V.B.2.d). *Requests by persons other than the NDA holder (§ 314.53(f)(1))* • Requires that a person submitting a patent listing dispute for a method-of-use patent include a statement of dispute that is only a narrative description (no more than 250 words) of the person's interpretation of the scope of the patent (see section V.B.4.a). • Requires that a person submitting a patent listing dispute directed to a drug substance, drug product, or method-of-use patent only include information in the statement of dispute for which the person consents to disclosure because FDA will send the text of the statement to the applicable NDA holder without review or redaction. • Requires that the NDA holder's response to a patent listing dispute directed to a drug substance, drug product, or method-of-use patent include a signed verification of the accuracy and completeness of the response (see section V.B.4.a). • Requires that the NDA holder's response to a patent listing dispute for a method-of-use patent also include a narrative description (no more than 250 words) of the NDA holder's interpretation of the scope of the patent that explains why the existing or amended "use code" describes only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. Requires that the narrative description only contain information for which the NDA holder consents to disclosure because FDA will send the text of the statement to the person who submitted the patent listing dispute without review or redaction (see section V.B.4.a). • Provides that FDA will promptly post information on its Web site regarding whether a patent listing dispute has been submitted for a published description of a patented method of use for a drug product and whether the NDA holder has timely responded to the patent listing dispute (see section V.B.4.a). • Omits the proposal to review a proposed labeling carve-out with deference to the 505(b)(2) and/or ANDA applicant(s)' interpretation of the scope of the patent in certain circumstances, which is not being finalized at this time (see section V.B.4.a).
314.54	*Procedures for submission of a 505(b)(2) application requiring investigations for approval of a new indication for, or other change from, a listed drug (§ 314.54(a)(1))* • Clarifies that the requirement for a 505(b)(2) applicant to identify one pharmaceutically equivalent drug product approved in an NDA as a listed drug (or an additional listed drug) relied upon applies before the date of submission of the original 505(b)(2) application and not a resubmission or a supplement (see section V.H).

Table 1.--Highlights of Substantive Changes From the Proposed Rule to the Final Rule--Continued

21 CFR Section in Final Rule	Description of Change From Proposed Rule See comment or section of this document (identified in parentheses) for more detailed information regarding the change.
314.60	*Patent certification requirements (§ 314.60(f))* • Requires that if an amendment to the 505(b)(2) application does not contain a patent certification or statement, the applicant must verify that the proposed change described in the amendment is not: (1) A new indication or other condition of use; (2) a new strength; (3) an other-than-minor change in product formulation; or (4) a change to the physical form or crystalline structure of the active ingredient (see section V.F.1).
314.70	*Patent certification requirements (§ 314.70(i))* • Omits proposed § 314.70(i) on patent certification requirements for 505(b)(2) supplements, which is not being finalized at this time (see section V.F.2).
314.90	*Waivers (§ 314.90)* • No substantive changes from the proposed rule (see section V.L).
314.93	*Petition to request a change from a listed drug (§ 314.93)* • No substantive changes from the proposed rule (see section V.I).
314.94	*Method-of-use patent (§ 314.94(a)(12)(iii)(A))* • Clarifies that an ANDA applicant may submit a statement under section 505(j)(2)(A)(viii) of the FD&C Act if the applicant is not seeking approval for "an" indication or other condition of use claimed by a method-of-use patent rather than "any" indications or other conditions of use claimed by the method-of-use patent (see section V.C.1). *Untimely filing of patent information (§ 314.94(a)(12)(vi))* • Provides that an amendment to the description of the approved method(s) of use claimed by the patent will not be considered untimely filing of patent information if the amendment is submitted within 30 days of a decision by the USPTO or a Federal court that is specific to the patent and alters the construction of a method-of-use claim(s) of the patent, and the amendment contains a copy of the decision (see section V.B.2.b). *After request to remove a patent or patent information from the list (§ 314.94(a)(12)(viii)(B))* • Omits the proposed requirement for a first applicant to lawfully maintain a paragraph IV certification to an original patent that has been reissued, which is not being finalized (see section V.B.1.e and V.E.3).
314.95	*Sending the notice of paragraph IV certification (§ 314.95(b))* • Deletes the reference to an "acknowledgment letter" in § 314.95(b)(1) and (b)(2) because an ANDA applicant will now receive a "paragraph IV acknowledgment letter" if the ANDA contains a paragraph IV certification before the ANDA is received (see section V.D.1.a). • Removes the requirement for an ANDA applicant to submit an amendment at the time it sends notice of a paragraph IV certification and permits submission of a single amendment that contains all required information within 30 days of the date on which the last notice is received (see section V.D.3.b).

Table 1.--Highlights of Substantive Changes From the Proposed Rule to the Final Rule--Continued

21 CFR Section in Final Rule	Description of Change From Proposed Rule See comment or section of this document (identified in parentheses) for more detailed information regarding the change.
314.96	*Patent certification requirements (§ 314.96(d))* • Clarifies that a paragraph IV certification to a patent or patent claim for which an ANDA applicant previously submitted a paragraph IV certification is a "recertification" rather than an "amendment" of the paragraph IV certification (see section V.F.3). • Requires that if an amendment to the ANDA does not contain a patent certification or statement, the applicant must verify that the proposed change described in the amendment is not: (1) a new indication or other condition of use; (2) a new strength; (3) an other-than-minor change in product formulation; or (4) a change to the physical form or crystalline structure of the active ingredient (see section V.F.1).
314.97	*Patent certification requirements (§ 314.97(c))* • Omits proposed § 314.97(c) on patent certification requirements for ANDA supplements, which is not being finalized at this time (see section V.F.2).
314.99	*Other responsibilities of an applicant of an ANDA (§ 314.99)* • No substantive changes from the proposed rule (see section V.L).
314.101	*Receiving an ANDA (§ 314.101(b))* • Clarifies current Agency practice that following a refuse-to-receive decision, an ANDA applicant may: Withdraw the ANDA under § 314.99; correct the deficiencies and resubmit the ANDA; or take no action, in which case FDA may consider the ANDA withdrawn after 1 year (see section V.J.2). • Omits the proposed administrative consequence for ANDA applicants who fail to send notice of paragraph IV certification within the statutory timeframe (see section V.J.3). *NDA or ANDA deficiencies (§ 314.101(d))* • Clarifies that FDA will consider the nature (e.g., major or minor) of the deficiencies, including the number of deficiencies in the ANDA in determining whether an ANDA is incomplete on its face (see section V.J.2). *Regulatory Deficiencies (§ 314.101(e))* • Clarifies that FDA will refuse to file a 505(b)(2) application or refuse to receive an ANDA if submission is not permitted under sections 505(c)(3)(E)(ii), 505(j)(5)(F)(ii), 505A(b)(1)(A)(i)(I), 505A(c)(1)(A)(i)(I), or 505E(a) of the FD&C Act (see section V.A.7).
314.105	*Approval of an NDA and an ANDA (§ 314.105)* • Removes the proposed statement that an NDA is approved on the date of the issuance of the approval letter, and clarifies that a new drug product may not be marketed until the "date of approval," rather than the "date of the approval letter" (see section V.A.3). • Clarifies that approval of a 505(b)(2) application or ANDA also may be delayed by a period of exclusivity for the listed drug under section 505E of the FD&C Act (see section V.A.7).

Table 1.--Highlights of Substantive Changes From the Proposed Rule to the Final Rule--Continued

21 CFR Section in Final Rule	Description of Change From Proposed Rule See comment or section of this document (identified in parentheses) for more detailed information regarding the change.
314.107	*Disposition of patent litigation (§ 314.107(b)(3))* • Revises § 314.107(b)(3)(v) to more clearly describe the timing of approval of a 505(b)(2) application or ANDA when a preliminary injunction is entered by a Federal district court before the expiration of a 30-month stay (or 7½ years where applicable) (see section V.M.2.g). • Clarifies that the 30-month period (or 7½ years where applicable) will be terminated if the court(s) enter(s) an order of dismissal without a finding of infringement in each pending suit for patent infringement brought within 45 days of receipt of the notice of paragraph IV certification sent by the 505(b)(2) or ANDA applicant (see section V.M.2.j). *Delay due to exclusivity (§ 314.107(d))* • Clarifies that approval of a 505(b)(2) application or ANDA also may be delayed by a period of exclusivity for the listed drug under section 505E of the FD&C Act (see section V.M.4). *Notification of court actions or written consent to approval (§ 314.107(e))* • Requires submission of a copy of any "written consent to approval" by the patent owner or exclusive patent licensee, rather than any "documented agreement," and clarifies that a copy of any order entered by the court terminating the 30-month or 7½-year period includes an order described in § 314.107(b)(3)(vii) and (viii) (see section V.M.5). • Provides that all information required by § 314.107(e)(1) must be sent to the applicant's NDA or ANDA rather than to OGD or the appropriate division in OND (see section V.M.5).
314.108	*New drug product exclusivity (§ 314.108)* • No substantive changes from the proposed rule.
314.125	*Refusal to approve an NDA (§ 314.125)* • Clarifies that FDA may refuse to approve a 505(b)(2) application if it does not contain a patent certification or statement with respect to each listed patent for a drug product approved in an NDA that is pharmaceutically equivalent to the drug product for which the original 505(b)(2) application is submitted and that was approved before the original 505(b)(2) application was submitted (see section V.H).
314.127	*Refusal to approve an ANDA (§ 314.127)* • No substantive changes from the proposed rule (see section V.L).
320.1	*Definitions (§ 320.1)* • No substantive changes from the proposed rule (see section V.A).
320.23	*Basis for measuring in vivo bioavailability or demonstrating bioequivalence (§ 320.23)* • No substantive changes from the proposed rule (see section V.N).

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IV. Legal Authority

The MMA and sections 505, 505A, 505E, 527, and 701 (21 U.S.C. 355, 355a, 355f, 360cc, and 371) of the FD&C Act provide the principal legal authority for this final rule. Section 505(b) of the FD&C Act describes the contents of an NDA, including a 505(b)(2) application, and describes patent listing and patent certification requirements for NDAs. Section 505(j) of the FD&C Act describes the contents of an ANDA, including bioequivalence information, patent certification requirements, and criteria for a petitioned ANDA. Section 505(b) and (j) of the FD&C Act restrict certain amendments and supplements to a 505(b)(2) application or an ANDA. Section 505(b), (c), and (j) of the FD&C Act describe the timing of approval for 505(b)(2) applications and ANDAs that are subject to certain patent and marketing exclusivity protections. Section 505(j) also describes the availability of 180-day exclusivity for a first applicant. Section 505(x) describes the date of approval of an NDA for which FDA intends to recommend controls under the Controlled Substances Act (CSA). Section 701(a) of the FD&C Act provides FDA with the authority to issue regulations for the efficient enforcement of the FD&C Act.

Section 505A of the FD&C Act describes the availability of pediatric exclusivity and describes the effect of such exclusivity on approval of 505(b)(2) applications and ANDAs. Section 505E of the FD&C Act describes the availability of an exclusivity period extension for certain designated qualified infectious disease products. Section 527 of the FD&C Act describes the effect of orphan exclusivity on approval of 505(b)(2) applications and ANDAs.

Thus, sections 505, 505A, 505E, and 527 of the FD&C Act, in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act, serve as our principal legal authority for this final rule.

V. Comments on the Proposed Rule and FDA Response

We received 13 comment letters on the proposed rule by the close of the comment period, each containing 1 or

more comments on 1 or more issues. We received comments from pharmaceutical industry associations, brand and generic drug manufacturers, law firms, and a law student. Several comments made general remarks supporting the proposed rule without focusing on a particular proposed provision.

We describe and respond to specific comments in sections V.A through V.O. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received. We also received comments on topics related to 505(b)(2) applications and ANDAs that are outside the scope of the proposed rule, including, for example, issues related to forfeiture of eligibility for 180-day exclusivity and the Drug Efficacy Study Implementation, and we are not addressing these comments at this time. We are currently implementing the 180-day exclusivity provisions of the MMA directly from the statute and will determine whether additional rulemaking is necessary in the future.

V.A. Definitions (§ 314.3(b))

We proposed to amend § 314.3(b) to define terms relevant to amendments to the FD&C Act made by the MMA and to add definitions of terms that have been used by the Agency in the context of implementing section 505(b) and (j) of the FD&C Act. We also proposed amendments to § 314.3(b) to conform with other changes in the proposed rule (80 FR 6802), and to incorporate new definitions. We received a general comment expressing support for FDA's efforts to clarify and update various definitions that are necessary for the efficient enforcement of the Hatch-Waxman Amendments. We received no comments on our proposed definitions of ''180-day exclusivity period,'' ''abbreviated new drug application or ANDA,'' ''active ingredient,'' ''ANDA holder,'' ''component,'' ''inactive ingredient,'' ''NDA holder,'' ''new drug application or NDA,'' ''original NDA,'' ''paragraph IV certification,'' ''patent owner,'' ''reference standard,'' ''strength,'' and ''therapeutic equivalents.'' We also received no comments on our proposed revisions to the current definitions of ''abbreviated application,'' ''act,'' ''applicant,'' ''application,'' ''listed drug,'' and ''the list.'' In addition, we received no comments on our proposed relocation of the definition of ''active moiety'' that currently is in § 314.108(a) to § 314.3(b). Finally, we received no comments on our proposed relocation of the definitions that currently are in § 320.1(a) and (c) through (g) to § 314.3(b), our proposed deletion of § 320.1(b), and our proposed revisions to the definitions of ''bioavailability'' and ''bioequivalence.'' Therefore, we are finalizing these definitions without change, except for the technical amendment to the definition of ''listed drug'' described in section V.A.3 (Response 4) and the technical amendments to the definitions of ''original NDA,'' ''resubmission,'' and ''therapeutic equivalents'' described in section V.P.1. We also describe a technical amendment to the definition of ''505(b)(2) application'' in section V.P.3 and the addition of the defined term ''Agency'' in section V.P.1.

V.A.1. Definitions of ''Acknowledgment Letter'' and ''Paragraph IV Acknowledgment Letter''

We proposed to establish a definition of the term ''paragraph IV acknowledgment letter'' and the related term ''acknowledgment letter'' to facilitate implementation of the MMA's requirement for a 505(b)(2) or ANDA applicant to send notice of a paragraph IV certification within 20 days after the date of the postmark on the notice with which FDA informs the applicant that the application has been filed (see section 505(b)(3)(B)(i) and (j)(2)(B)(ii)(I) of the FD&C Act and section V.A.6). We proposed to define ''paragraph IV acknowledgment letter'' to mean a written, postmarked communication from FDA to an applicant stating that the Agency has determined that a 505(b)(2) application or ANDA containing a paragraph IV certification is sufficiently complete to permit a substantive review. For 505(b)(2) applications and ANDAs that do not contain a paragraph IV certification, we proposed to define ''acknowledgment letter'' to mean a written, postmarked communication from FDA to an applicant stating that the Agency has determined that a 505(b)(2) application or ANDA is sufficiently complete to permit a substantive review. The proposed ''acknowledgment letter'' or ''paragraph IV acknowledgment letter'' would indicate that the 505(b)(2) application is regarded as filed or the ANDA is regarded as received (see proposed § 314.3(b)).

As explained in the proposed rule, the ''paragraph IV acknowledgment letter'' for 505(b)(2) applications that rely on the Agency's finding of safety and/or effectiveness for a listed drug and contain a paragraph IV certification would be the filing communication that generally is sent to the 505(b)(2) applicant not later than 14 calendar days after the 60-day filing date and sometimes is referred to as the ''74-day letter'' (see 80 FR 6802 at 6811 and 6814 to 6815). Unlike the paragraph IV acknowledgment letter for ANDAs, the filing communication is typically sent by the Office of New Drugs (OND) in the Center for Drug Evaluation and Research (CDER) in a franked envelope that may not bear a postmark made by the U.S. Postal Service (USPS). For purposes of § 314.52(b) and (c) only, we proposed that the ''date of the postmark'' on the ''paragraph IV acknowledgment letter'' would be considered to be four calendar days after the date on which the filing communication is signed by the signatory authority (generally the Division Director or designee in the OND review division), which generally reflects the date on which the document is received by the USPS (see definition of ''postmark'' in proposed § 314.3). In the proposed rule, we explained that if OND were to send the filing communication via electronic transmission in the future, then our proposed definition of a ''postmark'' that documents an electronic event would apply (see proposed § 314.3(b) and section V.A.6).

In the following paragraphs, we discuss a comment on these proposed definitions. We also received a comment that agrees with the proposed definition of ''paragraph IV acknowledgment letter'' and the inclusion of this term in revised § 314.101(b)(2). After considering these comments, we are revising the definition of ''acknowledgment letter'' to delete the reference to 505(b)(2) applications, thereby limiting the applicability of this term to ANDAs. We are finalizing the definition of ''paragraph IV acknowledgment letter'' without change.

(Comment 1) One comment requests that FDA clarify whether the terms ''acknowledgment letter,'' ''acceptance for filing letter,'' and ''paragraph IV acknowledgment letter'' can be used interchangeably to refer to the letter sent to applicants for ANDAs that contain a paragraph IV certification.

(Response 1) FDA separately defines the terms ''acknowledgment letter'' and ''paragraph IV acknowledgment letter'' for ANDAs because the ''paragraph IV acknowledgment letter'' contains

information on certain regulatory requirements associated with a paragraph IV certification. For administrative reasons, it had been FDA's practice to send an ''acknowledgment letter'' rather than a ''paragraph IV acknowledgment letter'' to an ANDA applicant if an original ANDA contained a patent certification or statement other than a paragraph IV certification, and the applicant submitted an amendment containing a paragraph IV certification before the ANDA has been received for substantive review. Accordingly, we proposed to use both terms in the regulations where appropriate (see proposed § 314.95). Upon further consideration, we are modifying our administrative practices to send a ''paragraph IV acknowledgment letter'' to an ANDA applicant if the ANDA contains a paragraph IV certification at any time prior to receipt of the ANDA. We are making conforming revisions to § 314.95(b)(1) and (2), (c)(3), and (d)(2) to remove the reference to an ''acknowledgment letter.'' We are retaining a revised definition of the term ''acknowledgment letter'' in § 314.3(b) because FDA's Office of Generic Drugs (OGD) will continue to send ''acknowledgment letters'' for ANDAs that do not contain a paragraph IV certification at the time of receipt (see, *e.g.,* section V.D.1.b). (The defined term ''acknowledgment letter'' for ANDAs differs from the informal use of this term for NDAs, which acknowledges the submission of an NDA before the Agency has determined whether the NDA can be filed.) FDA no longer uses the term ''acceptance for filing letter,'' which is an informal term that previously was used to describe an acknowledgment letter for an ANDA.

FDA has concluded that that it is unnecessary to distinguish between an ''acknowledgment letter'' and a ''paragraph IV acknowledgment letter'' for a 505(b)(2) application. If the 505(b)(2) application contains a paragraph IV certification at any time before the 505(b)(2) application is filed, the filing communication that FDA sends to NDA applicants also will be the ''paragraph IV acknowledgment letter'' for 505(b)(2) applicants for purposes of determining the date by which notice of paragraph IV certification must be sent (see § 314.52). We are making a conforming revision to § 314.52(d) to remove the reference to an ''acknowledgment letter'' (see section V.D.1.b).

V.A.2. Definition of ''Commercial Marketing''

We proposed to define ''commercial marketing'' to mean the introduction or delivery for introduction into interstate commerce of a drug product described in an approved ANDA, outside the control of the ANDA holder, except for investigational use under part 312 of this chapter (21 CFR part 312), but that does not include transfer of the drug product for reasons other than sale to parties identified in the approved ANDA (see proposed § 314.3(b)). In the following paragraphs, we discuss three comments on this proposed definition. After considering these comments, we are making editorial corrections to clarify the types of transfers of the drug product for reasons other than sale that fall within the exception to commercial marketing. We also are making amendments to clarify that the definition of commercial marketing includes the introduction or delivery for introduction into interstate commerce of the reference listed drug by the ANDA applicant.

(Comment 2) One comment recommends clarifying that commercial marketing does not include transfer of the drug product to a third-party logistics provider or contractor who is not identified in the ANDA, provided that the transfer does not take the drug product outside the control of the ANDA holder (*e.g.,* transfer of the drug product for storage or further distribution only as the ANDA holder may direct in the future). This comment also suggests revising the structure of the definition to improve clarity. Another comment maintains that the proposed definition would limit business flexibility, given that an ANDA applicant's transfer of the drug product to a re-packager (*e.g.,* to facilitate packaging validation or preparation for product launch) would be considered commercial marketing because re-packagers are not identified in ANDAs.

(Response 2) FDA declines to expand the exception to commercial marketing to include transfer of the drug product, outside the control of the ANDA applicant, for reasons other than sale to third parties not identified in the ANDA. FDA's amended definition of ''commercial marketing'' creates a bright-line rule for establishing the date of first commercial marketing of the drug by any first applicant for purposes of determining the start of the 180-day exclusivity period (see section 505(j)(5)(B)(iv)(I) of the FD&C Act and § 314.107(c)(2)). The amended definition also facilitates implementation of the statutory provision by which a first applicant may forfeit eligibility for 180-day exclusivity due to failure to market the drug by the timeframe described in the statute (see section 505(j)(5)(D)(i)(I) of the FD&C Act).

Under the amended definition in § 314.3(b), ''commercial marketing'' of the drug product refers to a transfer of the drug product outside the control of the ANDA applicant, subject to specified exceptions, and thus does not include a transfer of the drug product within the control of the ANDA applicant. As we explained in the proposed rule, the amended definition is intended to clarify that the ANDA applicant's shipment of a drug product described in an ANDA to any party named in the ANDA for purposes described in the ANDA (*e.g.,* contract packaging) is not ''commercial marketing'' of the drug product even though such transfer arguably places the drug products outside of the control of the manufacturer for some period of time (80 FR 6802 at 6812). Among other things, an ANDA holder would be required to identify a packager or re-packager in a supplement to the ANDA if different equipment or facilities are used that have a moderate potential to have an adverse effect on factors that may relate to the safety and effectiveness of the drug product (see 21 U.S.C. 356a and § 314.70(c); compare § 314.70(d)). We also note that storage and distribution facilities often are identified in ANDAs (see, *e.g.,* draft guidance for industry entitled ''Pre-Launch Activities Importation Requests (PLAIR)'' (July 2013) at 3, available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*). Accordingly, we do not expect the amended definition to have a significant impact on ANDA applicants' business arrangements with third parties.

FDA agrees that the definition of ''commercial marketing'' should be revised further for clarity. We also are making amendments to remove the reference to an ''approved'' ANDA and to further clarify that the definition of commercial marketing includes an ANDA applicant's commercial marketing of the reference listed drug, including an authorized generic drug (see section 505(j)(5)(B)(iv)(I) of the FD&C Act). As revised, commercial marketing is the introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA, outside the control of the ANDA applicant, except that the term does not include transfer of the drug product for investigational use under part 312 of this chapter or transfer of the

drug product to parties identified in the ANDA for reasons other than sale. Commercial marketing includes the introduction or delivery for introduction into interstate commerce of the reference listed drug by the ANDA applicant.

(Comment 3) One comment agrees with the proposed definition of ''commercial marketing'' but recommends specifically excluding charitable donations of drug product.

(Response 3) FDA disagrees with the recommendation to exclude charitable donations of drug product from the definition of ''commercial marketing.'' A drug product is introduced or delivered for introduction into interstate commerce, outside the control of the ANDA applicant, when an ANDA applicant donates the drug product to a charitable institution or organization (*e.g.,* a nonprofit hospital or health care entity). This introduction or delivery for introduction into interstate commerce subjects the donated drug product to applicable statutory and regulatory requirements, including, but not limited to, requirements intended to ensure that the drug product is not adulterated or misbranded (see, *e.g.,* 21 U.S.C. 331, 351, and 352). Moreover, even if the charitable institution or organization is identified in the ANDA, a charitable donation of drug product is not necessarily a transfer of the drug product for reasons other than sale, given that there are circumstances in which a donated drug product may be sold (see 21 U.S.C. 353(c)(3)(B) and 21 CFR 203.22). FDA does not believe the definition of ''commercial marketing'' will impact charitable donation of drug product, given that charitable donation of drug product met the criteria for commercial marketing under the previous definition in § 314.107(c)(4). The comment does not provide any explanation for the proposed change, and we do not believe that the proposed change is necessary.

V.A.3. Definition of ''Date of Approval''

We proposed to move the definition of ''date of approval'' from § 314.108(a) to § 314.3(b) with several revisions. We proposed that the date of approval would mean the date on the approval letter from FDA stating that the NDA or ANDA is approved (see proposed § 314.3(b)). Our proposed revisions broadened the definition to include the date of approval for an ANDA, and incorporated the defined term ''approval letter.'' We also proposed to remove the caveat that the date of approval is the date on the approval letter whether or not final printed labeling or other materials must still be submitted as long as approval of such labeling or materials is not expressly required.

In the following paragraphs, we discuss two comments that disagree with these proposed changes. After these comments were submitted, Congress enacted the Improving Regulatory Transparency for New Medical Therapies Act (IRTNMTA) (Pub. L. 114–89), which addresses the primary concern expressed by comments regarding the proposed revision to the definition. We are finalizing the definition with technical amendments to incorporate IRTNMTA.

(Comment 4) Two comments recommend that FDA retain the former definition of ''date of approval'' in § 314.108 because the definition addresses circumstances in which the date on the approval letter for an NDA is not the same as the date on which an applicable exclusivity period begins to run. The comments contend that the qualifying phrase ''as long as approval of such [final printed] labeling or materials is not expressly required'' in the former definition of ''date of approval'' is not reflected elsewhere in the Agency's regulations. Moreover, the comments assert that the proposed revision to the definition would effectively reduce the exclusivity period for certain approved drug products that cannot be commercially marketed until the Drug Enforcement Administration (DEA) has scheduled the drug as a controlled substance or until FDA has approved a proprietary name (where the name is necessary for the safe use of the drug). The comments maintain that FDA did not clearly describe and invite comment on these effects of the proposed revision to the definition.

(Response 4) We disagree with comments recommending that we retain the former definition of ''date of approval'' in § 314.108. As we explained in the proposed rule, FDA's regulations in § 314.105(b) specifically address the circumstances in which FDA will approve an NDA and issue the applicant an approval letter on the basis of draft labeling. Since publication of the proposed rule, FDA has determined that an ANDA also may be approved on the basis of draft labeling, provided that the only deficiencies in the draft labeling are editorial or similarly minor in nature (see guidance for industry entitled ''Acceptability of Draft Labeling to Support ANDA Approval'' (October 2015), available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*) (superseding FDA's former policy that final printed labeling is required for approval of an ANDA). If draft labeling deficiencies have not yet been resolved and are more than ''editorial or similar minor deficiencies,'' then the appropriate action is a complete response letter (see §§ 314.125(b) and 314.110). In the exceptional circumstances in which FDA has not yet approved a proprietary name for a proposed drug product and determines that the product cannot be marketed without a proprietary name, the applicant should receive a complete response letter (compare Letter from Janet Woodcock, M.D., Director, CDER, to Anil Hiteshi, Spectrum Pharmaceuticals, Inc., dated February 24, 2015, regarding Docket No. FDA–2014–P–1615, available at *http://www.regulations.gov*) (denying request for revision of the approval date because the approval letter expressly stated that Spectrum could market the product with labeling bearing only the established name until a proprietary name could be agreed upon). Accordingly, it is unnecessary to address any requirements for approval of final printed labeling in the definition of ''date of approval.''

On November 25, 2015, Congress enacted IRTNMTA, which addresses concerns that delays in scheduling a newly approved drug may reduce an applicable exclusivity period that commences on the ''date of approval.'' IRTNMTA provides that the date of approval for an NDA for which FDA intends to recommend controls under the CSA is the later of the date an NDA is approved under section 505(c) of the FD&C Act or the date of issuance of the interim final rule controlling the drug (see section 505(x)(1) and (2) of the FD&C Act). To incorporate IRTNMTA, we are revising the definition of ''date of approval'' to mean the date on the approval letter from FDA stating that the NDA or ANDA is approved, except that the date of approval for an NDA described in section 505(x)(1) of the FD&C Act is determined as described in section 505(x)(2) of the FD&C Act (see § 314.3(b)).

As reflected in the revised definition, we are currently implementing IRTNMTA directly from the statute and will determine whether additional rulemaking is necessary in the future. However, given the broader relevance of the term ''date of approval'' to matters covered in part 314, we are making other technical amendments to align with the revised definition and enhance clarity. These technical amendments are described in the following paragraphs.

We are further revising the proposed definition of ''listed drug'' to establish that a drug product is deemed to be a listed drug on the ''date of approval'' for the NDA or ANDA for that drug

product, rather than on the ''date of the approval letter'' (see § 314.3(b)). This technical amendment clarifies the listed drug status of a drug product described in section 505(x)(1) of the FD&C Act, and the corresponding date on which the drug product will be identified in the Orange Book (the list) as a listed drug. We are revising § 314.105(a) to remove the proposed statement that an NDA is approved on the date of the issuance of the approval letter. This statement may be inaccurate with respect to drug products described in section 505(x)(1) of the FD&C Act, and the text is unnecessary in light of the revised definition of ''date of approval'' (see § 314.3(b)). We also are revising § 314.105(a) to state that a new drug product may not be marketed until the date of approval, rather than the date of the approval letter, for consistency with IRTNMTA. Although section 505(x)(1) of the FD&C Act does not apply to ANDAs, we are making the same revisions to § 314.105(d) for consistency. In addition, we are revising § 314.107(b) to clarify that this provision describes how to determine the first possible date on which a 505(b)(2) application or ANDA can be approved, rather than the ''date of approval.'' We also are replacing the phrase ''the date the patented drug was approved'' with ''the date of approval'' in § 314.107(b)(3)(i)(B) to incorporate the revised definition. Finally, in the paragraph heading for § 314.108(b), we are replacing the phrase ''date of approval'' with ''timing of approval'' to more accurately characterize the content of this paragraph.

In the sections of parts 314 and 320 that are the subject of this rulemaking, the references to the ''date of approval'' are intended to refer to the revised definition in § 314.3(b). For example, we are maintaining the reference to ''date of approval'' in § 314.53(c)(2)(ii) to ensure that there is no ambiguity post-IRTNMTA about the required timeframe for submission of patent information after approval, given the implications of untimely filing of patent information on the patent certification obligations of 505(b)(2) applicants and ANDA applicants that rely upon the listed drug (see §§ 314.50(i)(4) and 314.94(a)(12)(vi)). Accordingly, for an NDA subject to IRTNMTA, the NDA holder must submit Form FDA 3542 within 30 days of the later of the date on which the NDA is approved under section 505(c) of the FD&C Act or the date of issuance of the interim final rule controlling the drug for the patent information to be considered timely filed.

V.A.4. Definition of ''Dosage Form''

We proposed to define ''dosage form'' to mean the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product. The physical manifestation includes such factors as: (1) The physical appearance of the drug product, (2) the physical form of the drug product prior to dispensing to the patient, (3) the way the product is administered, and (4) design features that affect frequency of dosing (see proposed § 314.3(b)). In the following paragraphs, we discuss a comment on this proposed definition. After considering this comment, we are finalizing the definition without change.

(Comment 5) One comment recommends that FDA broaden the definition of ''dosage form'' by including an additional factor to describe the physical manifestation of a drug product. The comment requests that FDA establish that a drug product with features that impart properties designed to deter tampering, abuse, or misuse of the drug product does not have the same dosage form as a similar version of the drug product that does not have such properties. The comment suggests that this would clarify that abuse-deterrent formulations and non-abuse-deterrent formulations of a drug product cannot be considered pharmaceutical equivalents or therapeutic equivalents.

(Response 5) FDA declines to adopt the comment's suggestion at this time. FDA may address issues related to the pharmaceutical equivalence and therapeutic equivalence of abuse-deterrent formulations of a drug product through rulemaking or other regulatory mechanisms.

V.A.5. Definitions of ''First Applicant'' and ''Substantially Complete Application''

We proposed to define the terms ''first applicant'' and ''substantially complete application'' to incorporate into our regulations the definitions established by the MMA, with minor editorial changes and additional clarifying text (see section 505(j)(5)(B)(iv)(II)(bb) and (cc) of the FD&C Act). We proposed to define ''first applicant'' to mean an applicant that, on the first day on which a substantially complete ANDA containing a paragraph IV certification is submitted for approval of a drug, submits a substantially complete ANDA that contains, and for which the applicant lawfully maintains, a paragraph IV certification for the drug (see proposed § 314.3(b)). We proposed to delete the definition of ''applicant submitting the first application'' in former § 314.107(c)(2) because that definition was superseded by the statutory definition.

We also proposed to define ''substantially complete application'' to mean an ANDA that on its face is sufficiently complete to permit a substantive review and contains all the information required under section 505(j)(2)(A) of the FD&C Act and § 314.94 (see proposed § 314.3(b)). We clarified that any information referenced in the ANDA must have been provided to FDA for the ANDA to be substantially complete, and we provided examples of other bases for finding that an ANDA is not substantially complete (see 80 FR 6802 at 6816 to 6817).

In the following paragraphs, we discuss a comment on these proposed definitions. After considering this comment, we are revising the definition of ''substantially complete application'' for consistency with § 314.101 and making an editorial correction for clarity. We are finalizing the definition of ''first applicant'' with editorial changes to more clearly incorporate the defined term ''substantially complete application.''

(Comment 6) One comment recommends that FDA revise the definitions of ''first applicant'' and ''substantially complete application'' to clarify the content required to support a decision that an ANDA is substantially complete ''on its face'' in order to distinguish deficiencies that may preclude receipt of an ANDA from review issues.

(Response 6) FDA is revising the definition of ''substantially complete application'' for consistency with other regulations outlining the required content of an ANDA and to enhance clarity. Under existing § 314.101(b), FDA will receive an ANDA if FDA finds that none of the reasons in § 314.101(d) and (e) applies for considering the ANDA not to have been received. The deficiencies described in § 314.101(d) that may result in refusal to receive an ANDA include, but are not limited to, an ANDA that is incomplete ''because it does not on its face contain information required'' under section 505(j) of the FD&C Act and § 314.94 (see § 314.101(d)(3)).

We are revising the definition of ''substantially complete application'' to include an express definition of ''sufficiently complete'' to permit a substantive review that aligns with our standard for receiving an ANDA. As revised, a ''substantially complete application'' is an ANDA that on its face is sufficiently complete to permit a substantive review. ''Sufficiently

complete'' to permit a substantive review means that the ANDA contains all the information required under section 505(j)(2)(A)(i) through (viii) of the FD&C Act and does not contain a deficiency described in § 314.101(d) and (e) (see § 314.3(b)). The phrase ''on its face'' describes FDA's threshold determination that the ANDA includes the information required to make it sufficiently complete to permit a substantive review (*i.e.,* information corresponding to the statutory and regulatory requirements for an ANDA). This evaluation does not involve a substantive review of the data in the ANDA (see § 314.101(b)(1)). As discussed in section V.J.2, we are supplementing § 314.101(d)(3) to more precisely describe the factors that FDA considers in determining whether an ANDA is incomplete on its face.

FDA is revising the definition of ''first applicant'' to more clearly incorporate the defined term ''substantially complete application.'' As revised, a first applicant is an ANDA applicant that, on the first day on which a substantially complete application containing a paragraph IV certification is submitted for approval of a drug, submits a substantially complete application that contains, and for which the applicant lawfully maintains, a paragraph IV certification for the drug.

V.A.6. Definition of ''Postmark''

We proposed to define the term ''postmark'' to address the MMA's requirement that a 505(b)(2) or ANDA applicant send notice of its paragraph IV certification within 20 days after the date of the postmark on the notice (*i.e.,* the paragraph IV acknowledgment letter) with which FDA informs the applicant that the application has been filed (see proposed § 314.3(b) and section 505(b)(3)(B)(i) and 505(j)(2)(B)(ii)(I) of the FD&C Act). The purpose of the postmark is to establish a verifiable date from which the 20-day notice period runs. In light of the transition by FDA and regulated industry to electronic communications, FDA proposed to define a ''postmark'' to mean an independently verifiable evidentiary record of the date on which a document is transmitted, in an unmodifiable format, to another party. For postmarks made by the USPS or a designated delivery service, the date of transmission is the date on which the document is received by the domestic mail service of the USPS or by a designated delivery service. For postmarks documenting an electronic event, the date of transmission is the date (in a particular time zone) that FDA sends the electronic transmission on its host system as evidenced by a verifiable record. If the sender and the intended recipient are located in different time zones, it is the sender's time zone that provides the controlling date of electronic transmission. In the following paragraphs, we discuss two comments on this proposed definition. After considering these comments, we are finalizing the definition without change.

(Comment 7) One comment recommends that FDA provide ANDA applicants with the option to receive a paragraph IV acknowledgment letter by electronic transmission rather than first class mail to help ensure prompt receipt by the ANDA applicant irrespective of location. The comment suggests that this option may reduce the likelihood that an ANDA applicant would fail to send notice of paragraph IV certification within 20 days after the date of the postmark on the paragraph IV acknowledgment letter, and thereby avoid the administrative consequence described in proposed § 314.101(b)(4). Another comment notes that the proposed definition of postmark clarifies the date by which notice of paragraph IV certification must be sent when ANDA applicants receive a paragraph IV acknowledgment letter from FDA both by electronic mail and the USPS.

(Response 7) We agree that electronic transmission of a paragraph IV acknowledgment letter to an ANDA applicant may facilitate timely sending notice of paragraph IV certification. Our definition of ''postmark'' is intended to accommodate the electronic transmission of paragraph IV acknowledgment letters from FDA to 505(b)(2) and ANDA applicants in the future.

OGD currently sends an ANDA applicant or its authorized representative a paragraph IV acknowledgment letter (or an acknowledgment letter, if appropriate) in an envelope bearing a postmark made by the USPS. If the ANDA applicant or its authorized representative has provided an electronic mail address on Form FDA 356h, which accompanies each submission to the ANDA, OGD also sends a courtesy copy of the paragraph IV acknowledgment letter (or an acknowledgment letter, if appropriate) by electronic mail and subsequently archives the electronic communication. Upon the effective date of this final rule (see section VI), the date of FDA's electronic transmission of a paragraph IV acknowledgment letter to an ANDA applicant also will be the postmark described in section 505(j)(2)(B)(ii)(I) of the FD&C Act. We no longer intend to send a paragraph IV acknowledgment letter to an ANDA applicant by the USPS. Accordingly, we expect few circumstances in which there will be a question about which postmark controls for purposes of determining the date by which notice of paragraph IV certification must be sent. However, if an ANDA applicant (or, in the future, a 505(b)(2) applicant) receives a paragraph IV acknowledgment letter from FDA both by electronic mail and the USPS, the earlier postmark provides the controlling postmark.

Although the comment did not discuss 505(b)(2) applications, we note that FDA is committed to adapting its business practices to evolving technology and anticipates electronically transmitting paragraph IV acknowledgment letters to 505(b)(2) applicants in a manner that meets the requirements of the definition of postmark in the future.

V.A.7. Definition of ''Tentative Approval''

We proposed to define ''tentative approval'' to mean the notification that an NDA (including a 505(b)(2) application) or ANDA otherwise meets the requirements for approval under the FD&C Act, but cannot be approved because a listed drug has unexpired orphan drug exclusivity, or that a 505(b)(2) application or ANDA otherwise meets the requirements for approval under the FD&C Act, but cannot be approved until the conditions in § 314.107(b)(1)(iii), (b)(3), or (c) are met, because the listed drug has a period of exclusivity under § 314.108 or section 505A of the FD&C Act, or because a court order under 35 U.S.C. 271(e)(4)(A) orders that the application may be approved no earlier than the date specified (see proposed § 314.3(b) and section 505(j)(5)(B)(iv)(II)(dd)(AA) of the FD&C Act). The proposed definition clarified that a drug product that is granted tentative approval is not an approved drug and will not be approved until FDA issues an approval letter after any necessary additional review of the NDA or ANDA. In the following paragraphs, we discuss a comment on this proposed definition. After considering this comment, we are revising the definition to describe an additional basis for tentative approval and making conforming revisions to §§ 314.101(e)(2), 314.105(a) and (d), and 314.107(b)(4) and (d).

(Comment 8) A comment requests that FDA update proposed § 314.107(d) to reflect that Generating Antibiotic Incentives Now (GAIN) exclusivity may delay approval of a 505(b)(2) application or ANDA, and that FDA make any other

necessary conforming revisions to the regulations.

(Response 8) We agree with the comment. Title VIII of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), entitled GAIN, provides an exclusivity period extension for certain designated qualified infectious disease products in section 505E of the FD&C Act. We are revising the definition of ''tentative approval'' to indicate that approval of a 505(b)(2) application or ANDA also may be delayed by a period of exclusivity for the listed drug under section 505E of the FD&C Act. We are making similar revisions to our regulations on approval of an NDA or ANDA (§ 314.105(a) and (d)) and delay due to exclusivity (§ 314.107(d)). We are also revising our regulations on tentative approval to explain that FDA will issue a tentative approval letter when tentative approval is appropriate in accordance with § 314.107 (see § 314.107(b)(4)).

GAIN also extends by 5 years the 4-year period described in section 505(c)(3)(E)(ii) and (j)(5)(F)(ii) of the FD&C Act after which certain 505(b)(2) applications or ANDAs containing a paragraph IV certification may be submitted. Accordingly, we are revising § 314.101(e)(2) to remove the cross-reference to § 314.108(b)(2) and expressly state that FDA will refuse to file an NDA or will consider an ANDA not to have been received if submission of a 505(b)(2) application or an ANDA is not permitted under section 505(c)(3)(E)(ii), 505(j)(5)(F)(ii), or 505E(a) of the FD&C Act. For completeness, we are making a technical amendment to § 314.101(e)(2) to reference pediatric exclusivity under section 505A(b)(1)(A)(i)(I) and (c)(1)(A)(i)(I) of the FD&C Act, which extends by 6 months the 4-year period described in section 505(c)(3)(E)(ii) and (j)(5)(F)(ii) of the FD&C Act.

V.B. Submission of Patent Information (§ 314.53)

V.B.1. General Requirements for Submission of Patent Information (§ 314.53(b) and (c))

Section 314.53(b) of our regulations requires that an applicant submitting an NDA, an amendment to an NDA, or, except as provided in § 314.53(d)(2), a supplement to an approved application, submit the patent information described in § 314.53(c) to its NDA on Forms FDA 3542a and 3542 with the filing or upon and after approval, respectively. The information requested in Form FDA 3542 must be provided for any patent that claims the approved drug substance, approved drug product, or any approved method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. FDA publishes certain information from Form FDA 3542 in the Orange Book after approval of the NDA or the supplement. The following sections describe our proposed revisions to these regulations and our responses to the comments that we received on the proposed rule.

V.B.1.a. *Drug substance (active ingredient) and drug product (formulation or composition) patents.* We proposed to revise § 314.53(c)(1) to omit the reference to ''complete'' patent information and clarify that FDA will accept a submission of patent information on Forms FDA 3542a or 3542, as appropriate, that omits requested patent information if the omission is permitted under an exception in § 314.53(c)(2). We proposed that an applicant need only satisfy the requirements for patent listing set forth in section 505(b)(1) and (c)(2) of the FD&C Act and, subject to the requirements for submission of method-of-use patent information, need not identify each basis on which the patent claims the drug (see proposed § 314.53(c)(2)(i)(S) and (c)(2)(ii)(T)). Accordingly, if a patent is eligible for listing as claiming both the drug substance and the drug product, an applicant only would be required to identify one of these two bases for listing. We proposed to clarify that these proposed exceptions to the required submission of patent information do not alter the requirements for submission of method-of-use patent information (see proposed § 314.53(c)(2)(i)(O)(*3*) and (c)(2)(ii)(P)(*4*)).

One comment supports these streamlined requirements for listing patents that claim the drug substance and/or drug product in the Orange Book. In the following paragraphs, we discuss two other comments on these proposed revisions. After considering these comments, we are finalizing these requirements without change. We are making conforming revisions to § 314.53(c)(2)(ii) to replace the phrase ''the patent declaration is incomplete'' with ''the patent declaration does not contain the required information.''

(Comment 9) One comment requests that FDA revise § 314.53(c)(1) to state that FDA will not accept patent information ''unless and until'' it is submitted on the appropriate form and contains the required information. The comment maintains that this revision would clarify that submission of patent information is considered complete only as of the date on which all required information has been submitted to FDA.

(Response 9) We decline to revise § 314.53(c)(1) as requested. FDA's existing regulations already require that if an NDA holder timely submits the required patent information, but FDA notifies the NDA holder that its Form FDA 3542 is incomplete or shows that the patent is not eligible for listing, the NDA holder must submit an acceptable Form FDA 3542 within 15 days of FDA's notification to be considered timely filed as of the date of the original submission of patent information (see § 314.53(c)(2)(ii)). FDA believes the current procedure is adequate to ensure timely and complete submission of patent information.

(Comment 10) One comment requests that FDA require additional detail regarding drug substance claims, where the drug product's active ingredient may not be self-evident. The comment also suggests that FDA require more detail regarding drug product claims to enable FDA to determine whether a new patent certification is required for a 505(b)(2) or ANDA applicant's change in product formulation and avoid an unwarranted opportunity for a 30-month stay.

(Response 10) The comment does not clearly describe the additional information requested or provide adequate support for any proposed change. FDA previously has explained that ''identification of the relevant patent(s), as opposed to the individual patent claims (other than for method-of-use patents), satisfies the [FD&C Act's] explicit requirements [and] provides sufficient information to potential applicants to determine if a more thorough patent search or analysis is warranted'' (''Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of [ANDAs] Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed; Final Rule'' 68 FR 36676 at 36685, June 18, 2003). (The MMA superseded certain provisions of the 2003 Final Rule related to 30-month stays of approval; the superseded regulations were subsequently revoked by technical amendment (see ''Application of 30-Month Stays on Approval of [ANDAs] and Certain [NDAs] Containing a Certification That a Patent Claiming the Drug Is Invalid or Will Not Be Infringed; Technical Amendment'' (69 FR 11309, March 10, 2004)).) Moreover, it is unnecessary for an NDA holder to submit more detailed patent information regarding drug product claims for purposes of determining whether a 505(b)(2) or

ANDA applicant must amend a previously submitted patent certification due to a change in the formulation of its proposed product because the 505(b)(2) or ANDA applicant has an independent duty to evaluate whether a previously submitted patent certification continues to be accurate after any change in the formulation of its proposed drug product. We also are adding §§ 314.60(f)(3) and 314.96(d)(3) to expressly describe when a change in product formulation requires an appropriate patent certification or a recertification (see section V.F.1).

V.B.1.b. *Drug substance patents that claim only a polymorph of the active ingredient.* We proposed to revise § 314.53(c)(2)(i)(M)(*2*) and (c)(2)(ii)(N)(*2*) to only require an applicant to provide information on whether the patent claims a polymorph (generally, a different crystalline or amorphous form of the same drug substance) that is the same active ingredient described in the NDA, amendment, or supplement if the only basis on which the patent is eligible for listing is that it claims the polymorph. We proposed conforming revisions to § 314.53(b)(1) and (2), (c)(2)(i)(M)(*3*), and (c)(2)(ii)(N)(*3*) to provide that the applicant's certification regarding test data required by § 314.53(b) applies only to patents that claim only a polymorph.

We received two comments that agreed with the proposed provision. In the following paragraphs, we discuss another comment on this proposed revision. After considering the comment, we are finalizing these revisions without change.

(Comment 11) One comment suggests that FDA require more specific information about the polymorph claimed in the patent that is the same active ingredient in the approved drug product to guide development of proposed products intended for submission in a 505(b)(2) application or ANDA.

(Response 11) The comment does not clearly describe the additional information requested; however, we disagree with the premise of the comment. FDA requires the NDA holder to submit information on Form FDA 3542 to enable the Agency to determine whether the patent or patent information is eligible for listing in the Orange Book based on the criteria in our regulations, to enable the Agency to implement section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act, and to assist the Agency with its administrative listing responsibilities. The drug substance and drug product designation for listing of a patent in the Orange Book is not intended to define the scope of patent claims that an NDA holder or patent owner may assert in patent infringement litigation against a 505(b)(2) or ANDA applicant (see § 314.53(c)(2)(ii)(T)). Each 505(b)(2) or ANDA applicant is responsible for conducting its own analysis of the scope of relevant patents.

V.B.1.c. *Method-of-use patents.* We proposed to revise § 314.53(b)(1) to further clarify that an NDA applicant or holder may submit a single Form FDA 3542a or Form FDA 3542, as appropriate, for a patent claiming more than one method of use, provided that each method of use is listed separately along with the patent claim number(s) of the patent claim(s) that corresponds to the pending or approved method of use.

We also proposed to revise our regulations to enhance compliance by NDA applicants and holders with the requirements for identifying the specific section(s) of product labeling that corresponds to the method of use claimed by the patent and, upon approval, describing the approved method of use claimed by the patent (the ''use code'') required for publication in the Orange Book (see proposed § 314.53(b)(1), (c)(2)(i)(O)(*2*), (c)(2)(ii)(P)(*2*) and (*3*)). To address situations in which the scope of the method of use claimed by the patent is narrower than an indication or other condition of use described in product labeling, we proposed to expressly require that if the scope of the method-of-use claim(s) of a patent does not cover every use of the drug, the applicant must identify only the specific sections of product labeling that correspond to the specific portion(s) of the indication or other condition of use claimed by the patent (see proposed § 314.53(b)(1)). We also proposed that if the scope of the method-of-use claim(s) of the patent does not cover every approved use of the drug, the NDA holder's use code must describe only the specific portion(s) of the indication or other method of use claimed by the patent (see proposed § 314.53(c)(2)(ii)(P)(*3*)). Finally, we proposed to codify the Agency's longstanding requirement that the NDA holder's use code must contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval (see proposed § 314.53(c)(2)(ii)(P)(*3*)).

Several comments support FDA's proposed revisions to the regulations regarding the submission of information on method-of-use patents. In the following paragraphs, we discuss other comments on the submission of information on method-of-use patents. After considering all of these comments, we are making clarifying revisions to § 314.53(b)(1), (c)(2)(i)(O)(*1*) and (*2*), (c)(2)(ii)(P)(*1*) through (*3*), and (e), and conforming revisions to Forms FDA 3542a and 3542.

(Comment 12) One comment suggests that the Agency's proposal regarding the required content of the use code appears to shift to the NDA holder the Agency's burden of determining whether a 505(b)(2) or ANDA applicant is not seeking approval for a protected use. Another comment objects to FDA's requirement that the NDA holder's use code contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval. The comment contends that this approach would require NDA holders to speculate about the protected uses that a prospective 505(b)(2) or ANDA applicant may seek to omit from labeling. Moreover, the comment asserts that this proposal is unworkable given that a 240-character use code may not adequately describe a series of patent claims of varying scope. The comment further notes that the use code does not obviate the need for the 505(b)(2) or ANDA applicant to evaluate the scope of the patent.

(Response 12) FDA disagrees with these comments regarding the content requirements for the use code. Given the Agency's ministerial role in patent listing, we require an NDA holder to provide adequate information about the scope of a listed method-of-use patent to assist 505(b)(2) and ANDA applicants in assessing whether the listed patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval and to enable FDA to evaluate whether a proposed labeling carve-out is appropriate (see section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act, respectively; see also *Caraco Pharm. Labs.* v. *Novo Nordisk A/S,* 132 S. Ct. 1670, 1684 (2012) (''Use codes are pivotal to the FDA's implementation of the Hatch-Waxman Amendments'')).

We are finalizing the requirement in § 314.53(c)(2)(ii)(P)(*3*) that the NDA holder's description of the patented method of use required for publication must contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval, with punctuation changes and clarifying revisions to the parenthetical example. We also are

expressly requiring that the NDA holder's description of the patented method of use meets the statutory standard for an NDA holder's submission of patent information (see section 505(b)(1) and (c)(2) of the FD&C Act). As revised, the parenthetical text explains that if the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, then the NDA holder must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product (see § 314.53(c)(2)(ii)(P)(*3*)). We are making conforming revisions to § 314.53(b)(1). The use code must only describe a patented method of use that is described in FDA-approved product labeling because the scope of the approved conditions of use of a drug product is described in the FDA-approved product labeling. We generally describe this content requirement for the use code as the ''specific approved method of use claimed by the patent.'' The development of the use code does not require speculation about the protected uses that a prospective 505(b)(2) or ANDA applicant may seek to omit from labeling; rather, it simply requires the NDA holder to describe only the specific approved method(s) of use claimed by the patent. This requirement also does not shift to the NDA holder the Agency's burden of determining whether a 505(b)(2) or ANDA applicant is not seeking approval for a protected use. Based on the use code provided by the NDA holder, FDA determines the specific labeling that describes the protected use and decides whether a 505(b)(2) application can be approved with that information omitted from the labeling or, in the case of an ANDA, whether an ANDA that omits the protected information from the labeling will be rendered less safe or effective for its remaining non-protected conditions of use (see § 314.127(a)(7)).

Given that the majority of use codes listed in the Orange Book do not approach 240 characters, this limitation is not expected to affect the accuracy of the NDA holder's description of the specific approved method(s) of use claimed by the patent. Nevertheless, FDA is expanding the use code character limit to 250 characters because FDA's database system can accommodate this additional text. We agree that the use code is not intended to substitute for the 505(b)(2) or ANDA applicant's review of the patent and the approved labeling in making decisions about whether to challenge a listed patent, request a delay in approval until expiry of the listed patent, or not request approval for a use claimed by the listed patent.

(Comment 13) One comment recommends that FDA clarify the directions on Form FDA 3542 for submitting the use code to avoid potential confusion about whether the NDA holder's use code should be based on language from the approved labeling or from the patent claim(s).

(Response 13) FDA agrees with the recommendation to clarify the instructions on Form FDA 3542 and the related regulations regarding the use code. We are revising § 314.53(b)(1) to clarify the general requirement that the NDA holder's description of the patented method of use required by § 314.53(c)(2)(ii)(P)(*3*) must describe only the approved method(s) of use claimed by the patent (see Response 12 for a discussion of the ''specific approved method of use claimed by the patent''). We also are revising § 314.53(c)(2)(i)(O)(*1*) and (c)(2)(ii)(P)(*1*) to remove the phrases ''or related indication'' and ''or indication,'' respectively, and supplementing § 314.53(c)(2)(ii)(P)(*3*) to clarify that the use code must describe only the specific approved method of use claimed by the patent. In other words, the scope of the use code must not extend beyond the scope of the patent claim(s) and, within the boundary established by the patent claim(s), the use code must only describe a patented method of use that has been approved by FDA as reflected in approved product labeling (see *Caraco Pharm. Labs.,* 132 S. Ct. 1670 at 1683, n.7 (rejecting an argument that the use code may sweep more broadly than the patent based on the requirement to provide a description of each approved method of use *or indication*) (emphasis added)). Consistent with our clarifying revisions to § 314.53(c)(2)(ii)(P)(*3*), we are revising section 4.2b of Form FDA 3542 to state that the NDA holder must submit the description of the specific approved method of use claimed by the patent that is proposed for inclusion as the ''use code'' in the Orange Book. We also are making conforming revisions to § 314.53(e) to replace the phrase ''approved indications or other conditions of use covered by a patent'' with the ''description of the method of use claimed by the patent as required by § 314.53(c)(2)(ii)(P)(*3*).''

(Comment 14) One comment proposes that FDA standardize use codes rather than relying on the NDA holder's description of the approved method of use claimed by the patent. Another comment recommends that FDA further describe its expectations for the content of use codes by providing hypothetical examples in which the patented method-of-use claim is broader, narrower, or co-extensive with an approved indication or other condition of use or that uses different terminology. The comment also suggests that FDA provide advice on the content of the use code where the method of use claimed by the patent is described in a section of labeling other than Indications and Usage.

(Response 14) We decline to adopt standardized use codes because we do not believe that standardized use codes would accurately capture the nuances of the method-of-use patent claims that NDA holders may submit to FDA for listing. FDA's role in listing patents remains ministerial (see ''Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions; Final Rule,'' 59 FR 50338 at 50349, October 3, 1994; see also 68 FR 36676 at 36687), and we continue to believe that there is a need for accurate and detailed information related to the approved methods of use claimed in the patent being submitted for listing (see 68 FR 36676 at 36682). Since 2003, when we began requiring NDA holders to submit the use code for publication in the Orange Book (see 68 FR 36676 at 36683), the Agency has gained significant experience in implementing section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act based on the NDA holder's use code. Based on our experience, we are clarifying the use code requirements through this rulemaking. We expect that these clarifying revisions to our regulations will improve the accuracy of use codes. As the U.S. Supreme Court noted in *Caraco Pharm. Labs.:* ''An overbroad use code . . . throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates'' (132 S. Ct. 1670 at 1684). Although we decline to provide hypothetical examples, the following general principles illustrate the clarifying revisions to the regulations regarding the content of use codes.

• *Patented method of use is broader than an indication or other approved condition of use:* The use code must only describe a patented method of use that is described in FDA-approved product labeling. If the method of use claimed by the patent uses different terminology than the approved labeling and/or is broader than an indication or other approved condition of use, then the use code would need to be phrased more narrowly than the patent claim to

only describe the specific patented method of use that is described in FDA-approved product labeling.

• *Patented method of use is co-extensive with an indication or other approved condition of use:* The use code must describe only the specific approved method of use claimed by the patent.

• *Patented method of use is narrower than an indication or other approved condition of use:* If the method of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, then the NDA holder must describe only the specific approved method of use claimed by the patent—not the broader indication or other approved condition of use that may include, but is broader than, the use claimed by the patent.

For example, Prandin (repaglinide) tablets currently are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, and U.S. Patent No. 6,677,358 (358 patent) was listed in the Orange Book as claiming a method of using Prandin. In *Novo Nordisk A/S* v. *Caraco Pharm. Labs.,* the Federal Circuit explained that claim 4 of the 358 patent ''claims '[a] method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin.' . . . An appropriate use code therefore must be limited to use of 'repaglinide in combination with metformin' to treat NIDDM'' (688 F.3d 766 at 768 (Fed. Cir. 2012)) (internal citation omitted). A similar approach would apply if the patented method of use is described in a section of labeling other than Indications and Usage. For example, if the patent claims a novel dosing regimen for a particular indication, the use code must specifically describe the protected dosing regimen for that indication and not only the indication to which the dosing regimen relates. Thus, if the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, an NDA holder's submission of a use code that describes an entire indication or other approved condition of use would violate FDA's regulations.

FDA requires the NDA holder to submit an accurate description, subject to the verification under penalty of perjury required by § 314.53(c)(2)(ii)(R), of the specific approved method of use claimed by the patent to implement section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act. An inaccurate description of the approved method of use claimed by the patent (*e.g.,* one that incorrectly describes the entire indication or condition of use to which the patented method of use relates rather than the specific approved method of use claimed by the patent) would impede FDA's ability to make a scientific determination about whether a 505(b)(2) application or ANDA may be approved with labeling that omits the protected information corresponding to the use code.

As described in § 314.53(b)(1), each approved method of use claimed by the patent must be separately identified and thus will require separate listing(s) of method-of-use information in section 4 of Form FDA 3542. We are revising Forms FDA 3542 and 3542a to facilitate separate listings of method-of-use information. We also are revising § 314.53(c)(2)(ii) to clarify the Agency will not list or publish patent information if it is not provided on Form FDA 3542.

(Comment 15) One comment requests that FDA clarify the level of detail with which an NDA applicant must identify the specific sections of product labeling that correspond to the specific portion(s) of the indication or other condition of use claimed by the patent. Another comment recommends that FDA replace the term ''specific sections'' with ''specific language'' and eliminate the parenthetical text in proposed § 314.53(c)(2)(i)(O)(*2*) and (c)(2)(ii)(P)(*2*) to clarify that the protected use may encompass less than the entirety of one of the ''sections'' of the product labeling. This comment also recommends that FDA replace the phrase ''corresponds to the method of use claimed by the patent'' with ''is claimed by the method of use claimed by the patent'' in proposed § 314.53(b)(1), (c)(2)(i)(O)(*2*), and (c)(2)(ii)(P)(*2*) to result in a more accurate identification of the specific labeling that describes a protected method of use.

(Response 15) FDA agrees that the regulations should clearly define the requirement to identify the specific labeling that describes the method of use claimed by the patent. FDA is revising its regulations to clarify that, for approved NDAs, the NDA holder submitting information on the method-of-use patent must identify with specificity the section(s) and subsection(s) of the approved labeling that describe the method(s) of use claimed by the patent submitted (see § 314.53(b)(1)). FDA is making conforming revisions to § 314.53(c)(2)(ii)(P)(*2*) and section 4.2a of Form FDA 3542 with respect to approved labeling, and to § 314.53(c)(2)(i)(O)(*2*) and section 4.2a of Form FDA 3542a with respect to proposed labeling.

Identifying the section(s) and subsection(s) of the approved labeling with specificity means listing on Form FDA 3542 (or, with respect to proposed labeling, Form FDA 3542a) each section and subsection of labeling that contains information describing the patented method of use.

• For prescription drug products with labeling in the ''physician labeling rule'' (PLR) format (see ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,'' 71 FR 3922, January 24, 2006), the section(s) and subsection(s) of the approved labeling should be identified by the section and subsection number (see 21 CFR 201.56(d) and 201.57). For example, ''section 1, subsection 1'' refers to the first indication listed in approved product labeling (see § 201.57(c)(2)).

• For prescription drug products with labeling not in PLR format, the section(s) and subsection(s) of the approved labeling should be identified by the section and subsection title (see §§ 201.56(b) and (e) and 201.80).

• For nonprescription drug products, the section(s) and subsection(s) of the approved labeling should be identified by the section and subsection title (see 21 CFR 201.66).

An NDA holder should evaluate whether FDA-approved revisions to product labeling (*e.g.,* conversion to PLR format) warrant submission of a revised Form FDA 3542 for the purpose of updating section 4.2a.

FDA agrees that the protected use may comprise less than the entirety of a section or subsection of the approved product labeling. However, it is unnecessary to require an NDA holder to identify the specific language in approved product labeling that describes the patented method of use because the use code and identification of the specific section(s) and subsection(s) of labeling that describe the patented method of use are sufficient for FDA to evaluate a 505(b)(2) or ANDA applicant's proposed labeling. Accordingly, FDA declines to replace the term ''specific sections'' with ''specific language'' in § 314.53(c)(2)(i)(O)(*2*) and (c)(2)(ii)(P)(*2*). FDA is removing the parenthetical text in proposed § 314.53(c)(2)(i)(O)(*2*) and (c)(2)(ii)(P)(*2*) because it is unnecessary in light of other clarifying revisions to the regulations regarding the use code.

If a 505(b)(2) or ANDA applicant submits a statement under section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act, FDA evaluates the 505(b)(2) or ANDA applicant's proposed labeling

to determine whether the applicant is not seeking approval for the protected use based on the use code submitted by the NDA holder and with reference to the labeling section(s) and subsection(s) identified by the NDA holder. FDA determines the specific labeling that describes the patented method of use, and decides whether the 505(b)(2) application can be approved with that information omitted from the labeling or, in the case of an ANDA, whether an ANDA that carves out the protected information from the labeling would be rendered less safe or effective than the listed drug for the remaining non-protected conditions of use and preclude approval (see § 314.127(a)(7)). For example, FDA has determined that it can approve ANDAs for broad, general indications that may partially overlap with a protected method of use, as long as any express references to the protected use are omitted from the labeling (see *Hospira, Inc.* v. *Burwell,* 2014 WL 4406901 at *17 (D. Md., Sept. 5, 2014) (upholding FDA's interpretation of section 505(j)(2)(A)(viii) of the FD&C Act)). Although identification of the section(s) and subsection(s) of labeling identified by the NDA holder may assist FDA in exercising its scientific judgment to implement section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act, FDA is not bound by the section(s) and subsection(s) identified by the NDA holder in section 4.2a of Form FDA 3542 in making its determination. FDA will use its independent scientific judgment to determine which section(s) and/or subsection(s) of labeling contain language that must be carved out based on the use code provided.

FDA agrees that the identified section(s) and subsection(s) of labeling should not merely ''correspond'' to the method of use claimed by the patent because the term ''correspond'' could be interpreted in an inappropriately broad manner. To enhance accuracy, FDA is revising § 314.53(b)(1), (c)(2)(i)(O)(*2*), and (c)(2)(ii)(P)(*2*) to require that the identified section(s) and subsection(s) of labeling ''describe'' the method of use claimed by the patent.

(Comment 16) One comment recommends that FDA require NDA holders to resubmit patent information on the updated Form FDA 3542 for all currently listed patents to maintain or revise the Orange Book listing. This comment also suggests that FDA request public comment on revisions to Forms FDA 3542a and 3542 to conform with the changes described in the proposed rule.

(Response 16) We disagree with the recommendation to require NDA holders to resubmit Form FDA 3542 for all currently listed patents to maintain their current Orange Book listings. Given that over 10,000 patent listings appear in the Orange Book, this recommendation would impose a significant burden on NDA holders and the Agency without a commensurate benefit. If a person seeks to confirm the accuracy or relevance of patent information currently listed in the Orange Book in light of the patent listing requirements set forth in § 314.53(b)(1) and (c), the person may submit a patent listing dispute under § 314.53(f)(1) (see section V.B.4.a). NDA applicants and holders will be required to submit patent information on the updated Forms FDA 3542a and 3542 on a prospective basis.

FDA requested public comment on its proposed revisions to the regulations and has made certain changes to the regulations in response to those comments. FDA is revising Forms FDA 3542a and 3542 to conform to the requirements established by this final rule.

V.B.1.d. *Patents previously submitted for listing.* We proposed to revise § 314.53(c)(2)(i)(J) and (c)(2)(ii)(K) to remove the requirement that an applicant provide information on whether the patent has been submitted previously for the NDA or supplement. We received no comments regarding this proposed revision; however, we have decided not to finalize this proposed change. Instead, we have decided to retain the existing requirement to assist the Orange Book staff with updating listed patent information where appropriate (see 68 FR 36676 at 36686 and ''Agency Information Collection Activities; Submission for [OMB] Review; Comment Request; Applications for [FDA] Approval to Market a New Drug . . . ,'' 72 FR 21266 at 21269, April 30, 2007).

V.B.1.e. *Reissued patents.* We proposed to require an NDA holder to submit additional information on patents that have been reissued by the USPTO under 35 U.S.C. 251. We proposed that an NDA applicant or holder must include information on whether a patent submitted for listing is a reissuance of a patent previously submitted for listing for the NDA or supplement (see proposed § 314.53(c)(2)(i)(J) and (c)(2)(ii)(K)). Our proposal reflected our consideration of the original patent and the reissued patent as a ''single bundle of patent rights,'' albeit patent rights that may have changed with reissuance, for purposes of administering the patent certification requirements of the FD&C Act and any 30-month stay of approval or 180-day exclusivity that relates to a paragraph IV certification to the original patent. In the following paragraphs, we discuss three comments on this proposal (see section V.E.3 for a discussion of comments on patent certification requirements for reissued patents). After considering these comments, we are not finalizing this proposal.

(Comment 17) The first comment recommends that FDA reevaluate its proposed regulations on reissued patents in light of a recent court decision rejecting FDA's ''single bundle of patent rights'' approach in a case involving the pre-MMA version of the FD&C Act. The second comment suggests that FDA further consider its ''single bundle of patent rights'' approach given the possibility for issuance of multiple patents based on continuing applications referring to the original patent application. The third comment supports the business certainty provided by FDA's ''single bundle of patent rights'' approach because the requirement for a 505(b)(2) or ANDA applicant to provide an appropriate patent certification or statement for a reissued patent would be governed by the provisions regarding untimely filed patents if either the original patent or the reissued patent was late-listed as to a pending 505(b)(2) application or ANDA.

(Response 17) FDA agrees that the ''single bundle of patent rights'' approach reflected in its proposed regulations on reissued patents should not be finalized in light of the recent decision in *Mylan Pharms., Inc.* v. *FDA,* 594 Fed. Appx. 791 (4th Cir. Dec. 16, 2014). In *Mylan,* the Court determined that a reissued patent ''is a separate grant of rights, even if elements of the reissued patent overlap with those of the original patent'' (see 594 Fed. Appx. 791 at 797). The Court held that the statutory reference to ''the patent which is the subject of the certification'' in the pre-MMA version of section 505(j)(5)(B)(iv) of the FD&C Act means that each patent (original and/or reissued) that is the subject of a paragraph IV certification may be a basis for eligibility for 180-day exclusivity.

Although the *Mylan* decision involved the pre-MMA version of the FD&C Act (in which eligibility for 180-day exclusivity was evaluated on a patent-by-patent basis), the Court's interpretation of ''the patent which is the subject of the certification'' is relevant to the current version of the FD&C Act when determining eligibility for first applicant status under the MMA's 180-day exclusivity scheme (see

section 505(j)(5)(B)(iii) of the FD&C Act). Accordingly, the Agency now considers reissued patents as separate and distinct from the original patent for purposes of administering the patent certification requirements of the FD&C Act and any 30-month stay of approval or 180-day exclusivity. Given that a reissued patent will be treated no differently than an original patent, it is unnecessary for FDA to require that an NDA holder's submission of patent information include information on whether the patent is a reissued patent of a patent previously submitted for listing, and we are not finalizing proposed § 314.53(c)(2)(i)(J) and (c)(2)(ii)(K).

Upon patent reissuance, the original patent is surrendered and ceases to have legal effect (see 37 CFR 1.178(a)). Thus, an NDA holder is required to withdraw the original patent and request that the original patent be removed from listing in the Orange Book after patent reissuance (see § 314.53(f)(2)). Consistent with our policy for any request to remove a patent from listing in the Orange Book, an original patent that has been reissued would remain listed in the Orange Book until FDA determined that no first applicant is eligible for 180-day exclusivity based on a paragraph IV certification to that patent or after the 180-day exclusivity period of a first applicant based on that patent has expired or has been extinguished.

V.B.2. When and Where To Submit Patent Information (§ 314.53(d))

V.B.2.a. *Submission of patent information for NDA supplements (§ 314.53(d)(2)).* We proposed to revise § 314.53(d)(2) to create two broad categories of supplements for purposes of required submission of patent information. For supplements that seek approval for a change that would result in a new entry in the Orange Book (*e.g.,* a change to the dosage form, route of administration, strength, or prescription drug status), we proposed that an applicant would continue to submit the complete patent information required under § 314.53(c) with submission of the supplement and following approval, respectively. For supplements that seek approval for another type of change (*e.g.,* to change the formulation, to add a new indication or other condition of use, or to make any other patented change regarding the drug substance, drug product, or any method of use that would not result in a new entry in the Orange Book), we proposed that the patent information submission requirements would depend on whether the existing patent information submitted to FDA for the product approved in the original NDA continued to claim the changed product.

If the patents listed for the approved NDA also claim the drug or method of using the drug for which approval is sought in the NDA supplement, we proposed that we would permit an applicant to submit a statement declaring that the patent(s) currently listed for a specific NDA (identified by NDA number and product number as listed in the Orange Book) continue to claim the drug or method of using the drug for which approval is sought in the NDA supplement, if this statement is accompanied by the signed patent declaration verification required by § 314.53(c)(2)(i)(Q) and (c)(2)(ii)(R) and if patent information required by § 314.53(c)(2)(ii) previously was submitted. If, however, a listed patent no longer claims the product as changed by the supplement, then we proposed that the applicant must submit a request to correct or remove the patent information from the list at the time of approval of the supplement (see proposed § 314.53(f)(2)). Correspondingly, if one or more existing patents claim the product as changed by the supplement and this patent information has not been submitted to FDA, we proposed that the applicant must submit the patent information with the supplement and following approval of the supplement. We proposed a conforming revision to § 314.70(f) to clarify that an applicant that submits a supplement to an NDA also must comply with the patent information requirements under § 314.53.

One comment supports the proposal because it would reduce duplicative submissions of patent information for supplements. We are finalizing proposed § 314.53(d)(2)(i) with an editorial change to clarify that § 314.53(d)(2)(i)(A) and (B) also apply to a supplement that seeks to add (rather than change) a dosage form, route of administration, or strength. To facilitate implementation of this provision, we are revising § 314.53(c)(2)(i)(F) and (c)(2)(ii)(F) to require that the NDA applicant or holder, respectively, identify the dosage form(s), route(s) of administration and whether the drug is proposed or approved for prescription use or over-the-counter (OTC) use in its submission of patent information. We are making conforming revisions to Forms FDA 3542a and 3542.

We are making several clarifying revisions to proposed § 314.53(d)(2)(ii). The proposed rule explained that we would permit an NDA holder to submit a statement declaring that the patent(s) currently listed for a specific NDA continue to claim the drug or method of using the drug for which approval is sought in the NDA supplement (instead of resubmitting the patent information with the NDA supplement), if this statement is accompanied by a signed patent declaration verification (see 80 FR 6802 at 6823). Consistent with the intent of the proposed rule to reduce duplicative submissions of patent information and enhance efficiency, we are not requiring an NDA holder to submit a statement with an NDA supplement if the NDA holder is not required to resubmit patent information pursuant to § 314.53(d)(2)(ii)(A). Accordingly, if an NDA supplement is approved for a change other than one of the changes listed in § 314.53(d)(2)(i) and the NDA holder does not submit Form FDA 3542 or submit a request to withdraw the patent or patent information from the list under § 314.53(f)(2)(iv) (see § 314.53(d)(2)(ii)(B) and (C)), FDA will consider the NDA holder to have affirmed that any currently listed patent(s) continues to claim the drug product as changed by the supplement. We are revising § 314.53(d)(2)(ii)(A) to clarify that patent information already submitted to FDA refers to information required by § 314.53(c). We also are revising § 314.53(d)(2)(ii)(A) to clarify that the requirement to resubmit patent information with a supplement if the description of the patented method of use would change upon approval of the supplement refers to the published description of the patented method of use (*i.e.,* the use code).

We are making a conforming revision to § 314.53(c) to clarify that if the applicant submits a supplement for a change other than one of the changes listed under § 314.53(d)(2)(i), then the patent information submission requirements of § 314.53(d)(2)(ii) apply (see § 314.53(c)(2)(i)(S)(*3*) and (c)(2)(ii)(T)(*3*)).

V.B.2.b. *Untimely filing of patent information (§§ 314.53(d)(3), 314.50(i)(4), and 314.94(a)(12)(vi)).* We proposed to revise our regulations regarding the submission of information on patents issued after the approval of an NDA or supplement to expressly describe our longstanding practice with respect to listing patent information that is not timely filed (see proposed § 314.53(d)(3)). Proposed § 314.53(d)(3) stated that if a patent is issued after approval and the required patent information is not submitted within 30 days of the issuance of the patent, FDA will list the patent, but patent certifications will be governed by the provisions regarding untimely filed

patents in §§ 314.50(i)(4) and (6) and 314.94(a)(12)(vi) and (viii). We also proposed to revise §§ 314.50(i)(4) and 314.94(a)(12)(vi) to state that, except as provided in § 314.53(f)(1), an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent (''use code'') will be considered untimely filing of patent information if:

- The amendment is submitted more than 30 days after patent issuance and it is not related to a corresponding change in approved product labeling; or
- The amendment is submitted more than 30 days after a corresponding change in approved product labeling.

Two comments agreed with this proposal. In the following paragraphs, we discuss two other comments on the proposal for certain amendments to the description of the approved method of use claimed by the patent to be considered untimely filing of patent information. After considering these comments, we are making clarifying revisions to the regulations and describing an additional set of circumstances in which an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent will not be considered untimely filing of patent information.

(Comment 18) One comment recommends that FDA withdraw its proposal, given that changes in patent law or interpretation, developments in patent-specific litigation, and/or proceedings before the USPTO may affect the scope of a patent claim's coverage and necessitate revisions to the use code. The comment notes that these events typically occur more than 30 days after patent issuance and do not involve a corresponding change in product labeling. Another comment recommends that FDA reevaluate its proposal to consider certain changes to the use code as untimely filed patent information in light of the lack of clarity on setting use codes.

(Response 18) We decline to withdraw our proposal given the important role of use codes in enabling a 505(b)(2) or an ANDA applicant to state that it is not seeking approval for the method of use claimed by the patent (see section 505(b)(2)(B) and (j)(2)(D)(viii) of the FD&C Act). However, we agree that revisions to the use code may be appropriate in other limited circumstances, as reflected in our revisions to §§ 314.50(i)(4) and 314.94(a)(12)(vi). Our approach is intended to enhance the accuracy of use codes and ensure that 505(b)(2) and ANDA applicants have timely notice of changes to the asserted patent coverage for a listed drug, while reducing opportunities for manipulation of patent use codes.

As a preliminary matter, we are revising the regulations to more clearly describe the circumstances in which an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent will not be considered untimely filing of patent information (see §§ 314.50(i)(4)(i)(A) and (B) and 314.94(a)(12)(vi)(A)(*1*) and (*2*)). As revised, an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent will be considered timely filed if it is submitted within 30 days of patent issuance or within 30 days of approval of a corresponding change to product labeling. We also are revising the regulations to provide that an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent will be considered timely filed patent information if it is submitted within 30 days of a decision by the USPTO or a Federal court that is specific to the patent and alters the construction of a method-of-use claim(s) of the patent (see §§ 314.50(i)(4)(i)(C) and 314.94(a)(12)(vi)(A)(*3*)). The amendment must contain a copy of the USPTO or court decision, and the accompanying Form FDA 3542 must identify the decision as a change related to the patent in section 1.h of the form (see the following discussion regarding revisions to § 314.53(c)(2)(i)(K) and (c)(2)(ii)(L)).

Our addition of §§ 314.50(i)(4)(i)(C) and 314.94(a)(12)(vi)(A)(*3*) permits NDA holders to make timely revisions to the use code based on a patent-specific decision by the USPTO (*e.g.,* inter partes review, post-grant review, and reexamination) or by a Federal court (*e.g., Markman* hearing) that construes the terms of the patent claim(s). An NDA holder may submit a revised use code based on a patent-specific decision by either a Federal district court, the Court of Appeals for the Federal Circuit, or the U.S. Supreme Court. We decline to broaden the scope of this provision to allow for use code changes to be considered timely filed based solely on changes in patent law or interpretation that are not specific to the patent for which the use code was submitted because we are not experts in patent law and would be unable to evaluate arguments that could effectively remove the limitation for untimely filing of method-of-use patent information.

Our clarifying revisions to the regulations are expected to address concerns about how to set use codes, and there is no need to reevaluate our proposal on this basis.

To facilitate implementation of this provision, FDA is revising § 314.53(c)(2)(i)(K) and (c)(2)(ii)(L) to require that if the patent has been submitted previously for listing, the NDA holder must identify all change(s) from the previously submitted patent information and specify whether the change is related to the patent (*e.g.,* patent term extension or patent-specific decision by the USPTO or a Federal court) or related to an FDA action or procedure (*e.g.,* FDA approval of a supplement that changes the approved conditions of use of the drug). This information will assist the Orange Book staff in updating listed patent information where appropriate and replaces the current requirement that an applicant only identify whether the expiration date is a new expiration date.

We also are making technical amendments in §§ 314.50(i)(4) and 314.94(a)(12)(vi) to explain that a 505(b)(2) or ANDA applicant generally is not required to submit a patent certification *or statement* to address the patent or *patent information* that is late-listed with respect to the pending 505(b)(2) application or ANDA. Although a patent certification or statement generally would not be required in this circumstance, we would permit an applicant to submit and maintain a patent certification (including a paragraph IV certification) or a statement pursuant to section 505(b)(2)(B) or 505(j)(2)(B)(viii) of the FD&C Act, if desired. For example, an ANDA applicant may wish to submit a paragraph IV certification to challenge the method-of-use patent with the revised use code if the applicant may be eligible for 180-day exclusivity based on that certification.

V.B.2.c. *Where to send submissions of Forms FDA 3542a and 3542 (§ 314.53(d)(4)).* We proposed to clarify that patent information submitted on Form FDA 3542a with the filing of an NDA, amendment, or supplement must be submitted to the CDER Central Document Room, and should not be submitted to the Orange Book staff (see proposed § 314.53(d)(4)(i); see also §§ 314.50(h) and 314.70(f)). We also proposed to require that patent information submitted on Form FDA 3542 upon and after approval of an NDA or supplement be submitted directly to the Orange Book staff through the OGD Document Room. Our proposal to designate the OGD Document Room as the official repository for submission of Form FDA 3542 was intended to facilitate prompt listing of patent information in the Orange Book after Form FDA 3542 has been officially

received by the Agency (see proposed § 314.53(d)(4)(ii) and (d)(5)).

In the following paragraphs, we discuss a comment on these proposed revisions. After considering this comment, we are finalizing § 314.53(d)(4)(ii) with revisions to maintain the CDER Central Document Room as the official repository for submission of Form FDA 3542 and we are finalizing § 314.53(d)(4)(i) and (ii) to clarify that Forms FDA 3542a and 3542 can be submitted electronically. We also are finalizing § 314.53(d)(4)(i) and (ii) with an editorial correction to the title of Forms FDA 3542a and 3542, and we are making the same correction in § 314.53(f)(2)(ii) through (iv).

(Comment 19) One comment requests confirmation that NDA holders may submit Form FDA 3542 to the OGD Document Room through the Electronic Submissions Gateway (ESG). The comment also recommends that FDA clarify that Form FDA 3542a must be submitted to the NDA via CDER's Central Document Room.

(Response 19) FDA is revising § 314.53(d) to expressly provide that Form FDA 3542 can be submitted in an electronic format submission that complies with § 314.50(l)(5), which permits submission through the ESG. This revision and the corresponding revision to § 314.53(d)(5) are intended to clarify how submission dates are determined for Form FDA 3542, given the implications of untimely filing of patent information on the patent certification obligations of 505(b)(2) and ANDA applicants that rely upon the listed drug (see §§ 314.50(i)(4) and 314.94(a)(12)(vi)). Beginning in May 2017, Form FDA 3542 and other submissions under section 505(b), (i), and (j) of the FD&C Act must be submitted in the electronic format specified by FDA (see section 745A(a) of the FD&C Act (21 U.S.C. 379k–1(a)) and guidance for industry entitled ''Providing Regulatory Submissions in Electronic Form—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (May 2015), available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*). Accordingly, we only have specified the method of submission where it is important to describe how receipt dates or submission dates are determined for a particular type of submission.

Based on the transition to electronic submission of Form FDA 3542 and related changes in FDA's administrative processes, we are not finalizing our proposal to change the official repository for submission of Form FDA 3542. Thus, Form FDA 3542 must continue to be submitted to the NDA via the CDER Central Document Room or the ESG. The CDER Central Document Room and the ESG promptly direct submissions of Form FDA 3542 to the Orange Book staff for listing in the Orange Book. To ensure that patents and patent information are listed in the Orange Book only after Form FDA 3542 has been officially received by FDA, the Orange Book staff intends to rely only on submissions of Form FDA 3542 that are received from the Central Document Room and disregard any duplicate copies or courtesy copies of Form FDA 3542 that are submitted through other channels. We are revising § 314.53(d)(4)(ii) to emphasize that Form FDA 3542 should not be submitted to the Orange Book staff.

V.B.2.d. *Submission date of patent information (§ 314.53(d)(5)).* We proposed to revise § 314.53(d)(5) to establish that the submission date of patent information provided by an NDA holder after approval of an application is the earlier of the date on which Form FDA 3542 is date-stamped by the OGD Document Room or officially received electronically by FDA through the ESG (*i.e.,* at the completion of electronic transmission). We proposed that patent information sent to another location at FDA would not be considered received by FDA for purposes of § 314.53(d)(3) on timely filing and a 505(b)(2) or ANDA applicant's patent certification obligations pursuant to § 314.50(i)(4) and (6) or § 314.94(a)(12)(vi) and (viii), respectively, unless it is sent to the official repository identified in the regulation. In the following paragraphs, we discuss two comments on this provision. After considering these comments, we are finalizing § 314.53(d)(5) with revisions unrelated to the comments to conform to the changes made to § 314.53(d)(4)(ii).

(Comment 20) One comment suggests that FDA provide a list of untimely filed patent information to facilitate evaluation of patent certification obligations by 505(b)(2) and ANDA applicants. Another comment recommends that FDA include in the Orange Book the date on which the patent information was submitted to FDA.

(Response 20) FDA agrees that modifying the Orange Book to list the date on which patent information was submitted to FDA as described in § 314.53(d)(5) would enable applicants to determine whether a patent is late-listed as to a pending 505(b)(2) application or ANDA and avoid the need for applicants to contact the Orange Book staff for this information. FDA intends to list the date of submission of patents and patent information in the Orange Book on a prospective basis beginning as soon as practicable after the effective date of this rule. This addition to the Orange Book does not require any modification to the regulations. FDA does not intend to separately publish a list of untimely filed patent information.

V.B.3. Public Disclosure of Patent Information (§ 314.53(e))

We proposed technical corrections to § 314.53(e) to delete the reference to monthly supplements to the Orange Book and clarify that copies of the ''submitted patent information'' (rather than copies of the ''file'') may be requested from FDA's Freedom of Information Staff. We also proposed to expressly state that the submitted patent information, and requests for delisting patents, will be subject to public disclosure (see proposed § 314.53(e)). In the preamble to the proposed rule, we explained that FDA may elect to proactively post on FDA's Web site a copy of the submitted patent information (Form FDA 3542) for listed patents in advance of a request under the Freedom of Information Act (FOIA) based on our anticipation of requests for this information. In the following paragraphs, we discuss a comment on the potential for proactive posting of Form FDA 3542 on FDA's Web site. After considering this comment, we are making an editorial correction to clarify the information that may be subject to public disclosure.

(Comment 21) One comment urges FDA not to proactively post Form FDA 3542 on the FDA Web site based on concerns that the patent information could be misused or lead to misinterpretation of the scope of relevant patent rights in litigation or commercial contexts.

(Response 21) FDA is not persuaded by the comment, given that Form FDA 3542 must contain the verification required by § 314.53(c)(2)(ii)(R) and may be subject to disclosure under FOIA and applicable disclosure regulations. Moreover, FDA has advised prospective 505(b)(2) and ANDA applicants that the use code and other information provided on Form FDA 3542 is not meant to substitute for the applicant's review of the patent. However, at this time, FDA does not intend to proactively post Form FDA 3542 for patent information submitted for listing in the Orange Book because there is an adequate mechanism to obtain a Form FDA 3542 on an individual basis through a FOIA request. We are revising § 314.53(e) to clarify that the submitted

patent information and requests to remove a patent or patent information from the list may be subject to public disclosure.

V.B.4. Correction or Change of Patent Information (§ 314.53(f))

V.B.4.a. *Requests by persons other than the NDA holder (§ 314.53(f)(1)).* We proposed to revise § 314.53(f) to clarify and improve the mechanism for challenging the accuracy or relevance of patent information submitted to the Agency under § 314.53 and listed in the Orange Book (see proposed § 314.53(f)(1)). First, we proposed to establish a 30-day timeframe in which the NDA holder would be required to respond to FDA's request to confirm the correctness or omission of patent information to facilitate timely resolution of the patent listing dispute. Second, we proposed enhanced procedures to govern challenges to the accuracy or relevance of an NDA holder's submission of method-of-use patent information so that the Agency has additional information to implement section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act in cases where the accuracy or relevance of the use code is disputed (see proposed § 314.53(f)(1)).

For a patent listing dispute regarding method-of-use patent information, we proposed to ask the NDA holder to confirm the correctness of its description of the approved indication or method of use that has been included as the ''use code'' in the Orange Book, and provide information on the specific approved use claimed by the patent that would enable the Agency to make a determination in accordance with section 505(b)(2)(B) or (j)(2)(A)(viii) of the FD&C Act (see proposed § 314.53(f)(1)). We proposed that if the NDA holder confirms the accuracy of its submitted patent information in response to FDA's request, fails to timely respond to the request, or submits a revision to the use code that does not provide adequate clarity for FDA to determine whether the scope of a proposed labeling carve-out would be appropriate based on the NDA holder's use code and approved labeling, FDA would review a proposed labeling carve-out(s) for the 505(b)(2) application or ANDA with deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent. In such a case, we explained that FDA would consider the use code and labeling information submitted by the NDA holder on Form FDA 3542, the history of labeling changes related to approval of an indication(s) for the drug product, the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent, the need for consistent labeling among products approved under section 505(j) of the FD&C Act, and the requirements of §§ 314.94(a)(8)(iv) and 314.127(a)(7), as appropriate.

Two comments support FDA's proposed revisions to the patent listing dispute procedure. In the following paragraphs, we discuss several other comments on this proposal. After considering these comments, we are revising § 314.53(f)(1) to describe the rules that will apply to patent listing disputes involving drug substance, drug product, and method-of-use claims. We also are revising § 314.53(c)(2)(ii)(R) to expressly state that the requirement to verify the accuracy and completeness of the submission of patent information applies to a response to a patent listing dispute under § 314.53(f)(1). We intend to take a stepwise approach and evaluate whether FDA's revisions to the regulations on submission of method-of-use patent information (see § 314.53(b)(1) and (c)(2)) and patent listing dispute procedures adequately address the problem of overbroad and ambiguous use codes before we establish a process to review a proposed labeling carve-out with deference to the 505(b)(2) and/or ANDA applicant(s)' interpretation of the scope of the patent. Therefore, at this time, we are not finalizing our proposal to review a proposed labeling carve-out with deference to the applicant(s)' interpretation of the scope of the patent in certain circumstances. We will continue to consider whether there is a need to finalize this proposal in the future.

(Comment 22) Three comments indicate that there are inconsistencies between the text of proposed § 314.53(f) and the process described in the corresponding preamble, and request that FDA clarify the circumstances in which the Agency proposes to review a proposed labeling carve-out for a 505(b)(2) application or ANDA with deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent. Several comments contend that it is inappropriate to defer to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent where the NDA holder has confirmed the accuracy of the use code. One comment asserts that this approach will encourage 505(b)(2) and ANDA applicants to routinely dispute method-of-use patent information in an attempt to receive deference on a narrow interpretation of the method-of-use patent and submit a statement under section 505(b)(2)(B) or (j)(2)(A)(viii) of the FD&C Act instead of a patent certification. One comment also contends that the Agency's standard for determining that an NDA holder's revision to the use code ''does not provide adequate clarity'' or determining that there is ''insufficient information'' to evaluate a proposed labeling carve-out is impermissibly vague.

(Response 22) FDA has made multiple changes to address the issue of overbroad and ambiguous use codes, including revisions to the regulations on submission of patent information and revisions to the patent listing dispute procedures (see sections V.B.1.c and V.B.2.b). We initially intend to evaluate whether these revisions to the regulations adequately address the problem of overbroad and ambiguous use codes. If these revisions to our regulations do not adequately address the problem, we will further consider whether to finalize the proposal to review a proposed labeling carve-out for a 505(b)(2) application or ANDA with deference to the 505(b)(2) and/or ANDA applicant(s)' interpretation of the scope of the patent. If FDA decides to finalize the proposal, FDA would clarify the process and the circumstances in which such deference may be given.

We are revising the regulation to provide a more detailed description of the procedure for patent listing disputes directed to the accuracy or relevance of submitted patent information regarding an approved method of using the drug product (see § 314.53(f)(1) and (f)(1)(i)(B); see also § 314.53(f)(1)(i)(A) (describing patent listing dispute procedures directed to drug substance or drug product claims)). We also are revising § 314.53(c)(2)(ii)(R) to expressly state that the requirement that an NDA holder verify the accuracy and completeness of the submission of patent information applies to a response to a request under § 314.53(f)(1). This regulatory approach is intended to provide the Agency with additional information to facilitate implementation of section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act (see section 701(a) of the FD&C Act).

For all patent listing disputes, we are requiring that the patent listing dispute communication contain a statement of dispute that describes the specific grounds for disagreement regarding the accuracy or relevance of patent information for FDA to send to the applicable NDA holder. If a person disputes the accuracy or relevance of submitted patent information regarding an approved method of using the drug product, this statement of dispute must be only a narrative description (no more than 250 words) of the person's

interpretation of the scope of the patent with respect to the method of use.

FDA intends to forward the statement of dispute (without review or redaction) to the applicable NDA holder using the electronic mail (email) address or facsimile (fax) number provided by the NDA holder on the most recent Form FDA 356h submitted to the NDA. Therefore, the person submitting the patent listing dispute communication should clearly identify the statement of dispute that he or she intends for FDA to send to the applicable NDA holder, and only include information for which the person consents to disclosure.

- For patent listing disputes directed to drug substance or drug product claims, the NDA holder must confirm the correctness of the patent information and include the signed verification required by § 314.53(c)(2)(ii)(R) or withdraw or amend the patent information in accordance with § 314.53(f)(2) within 30 days of the date on which the Agency sends the statement of dispute. Although proposed § 314.53(f)(1) would have permitted disputes over the omission of patent information, it is unnecessary for FDA to request the NDA holder to confirm the omission of patent information for a listed patent because we no longer require an NDA holder to identify whether a patent claims both the drug substance and the drug product (see § 314.53(c)(2)(ii)(T)). Accordingly, we are making a conforming amendment to remove the phrase ''or omission of patent information'' from § 314.53(f)(1)(i)(A). Unless the NDA holder withdraws or amends its patent information in response to the patent listing dispute, the Agency will not change the patent information in the Orange Book (see § 314.53(f)(1)(i)(A)).
- For patent listing disputes directed to method-of-use claims, the NDA holder must confirm the correctness of the NDA holder's description of the approved method of use claimed by the patent that has been included as the ''use code'' in the Orange Book or withdraw or amend the patent information in accordance with § 314.53(f)(2). In either case, the NDA holder must provide a narrative description (no more than 250 words) of the NDA holder's interpretation of the scope of the patent that explains why the existing or amended ''use code'' describes only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. The NDA holder must also include the signed verification required by § 314.53(c)(2)(ii)(R) and submit its response within 30 days of the date on which the Agency sends the statement of dispute (see § 314.53(f)(1)(i)(B)). Any response from the NDA holder that is submitted after 30 days will be considered untimely. The narrative description must only contain information for which the NDA holder consents to disclosure because FDA will send the text of the statement to the person who submitted the patent listing dispute without review or redaction to further assist the person (generally a 505(b)(2) or ANDA applicant, a prospective applicant, or its representative) in determining whether a use for which an applicant may seek approval is a protected use.

We are revising the regulation to clarify that if the NDA holder timely responds to the patent listing dispute with a confirmation of the correctness of the patent information, the narrative description required by § 314.53(f)(1)(i)(B), and the signed verification required by § 314.53(c)(2)(ii)(R), the Agency will not change the patent information in the Orange Book (see § 314.53(f)(1)(i)(B)(*1*)). We are also revising the regulation to more clearly state that if the NDA holder timely responds to FDA's request with revised patent information, the narrative description required by § 314.53(f)(1)(i)(B), and the signed verification required by § 314.53(c)(2)(ii)(R), FDA will update the Orange Book to reflect the revised patent information (see § 314.53(f)(1)(i)(B)(*2*) and Response 26). This approach provides additional clarity, and establishes a mechanism for a person (including a 505(b)(2) or ANDA applicant) to request that an NDA holder confirm compliance with the updated requirements for submission of patent information described in § 314.53(b) and (c).

A 505(b)(2) application or ANDA must contain an appropriate certification or statement for each listed patent, including the disputed patent, during and after the patent listing dispute (see § 314.53(f)(1)(ii)). A disputed method-of-use patent may continue to be the subject of a paragraph IV certification. We do not believe that an ongoing patent listing dispute process will have an impact on the timing of approval of a 505(b)(2) application or ANDA that is otherwise eligible for approval and relies on the listed drug for which the disputed patent is listed in the Orange Book. FDA may consider the narrative description from the NDA holder required by § 314.53(f)(1)(i)(B), as appropriate, to assist FDA in exercising its scientific judgment to implement section 505(b)(2)(B) and (j)(2)(A)(viii) of the FD&C Act.

To advise prospective and pending 505(b)(2) or ANDA applicants of a patent listing dispute involving a method-of-use patent, FDA will promptly post information about the patent listing dispute on a Web page linked to the Orange Book. FDA intends to provide information such as the relevant drug product, NDA number, NDA holder, U.S. Patent Number, relevant use code(s), and whether the NDA holder has timely responded to the patent listing dispute (see § 314.53(f)(1)(iii)).

(Comment 23) Three comments recommend that FDA withdraw or revise the proposal to review, in certain circumstances, a proposed labeling carve-out for a 505(b)(2) application or ANDA with deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent. One comment contends that there is no basis for FDA's proposed approach because the statutory scheme contemplates that disputes over the scope of a method-of-use patent will be resolved by Federal courts in patent infringement litigation, especially given that the MMA established a counterclaim procedure in which a 505(b)(2) or ANDA applicant may seek an order requiring the NDA holder to correct or delete the submitted patent information. Another comment maintains that it would be legally inappropriate for FDA to defer to the 505(b)(2) or ANDA applicant's view of the scope of a patent that the applicant does not own, especially if the NDA holder has confirmed the accuracy of the use code. Two comments suggest that when patent listing disputes arise, FDA should seek clarification or correction of patent information through other means.

(Response 23) We believe that FDA has the authority to establish a regulation describing the limited circumstances in which the Agency would defer to the 505(b)(2) or ANDA applicant's interpretation of the scope of a patent that it does not own. However, in light of the incremental approach that we are taking to this issue, we are not finalizing this aspect of our proposal at this time. We will continue to consider whether there is a need to finalize this proposal in the future.

The statutory provisions that permit a 505(b)(2) or ANDA applicant to submit a statement that a listed patent does not claim a use for which the applicant is seeking approval complement the patent certification requirements (see section 505(b)(2)(A) and (B) and (j)(2)(A)(vii)

and (viii) of the FD&C Act). FDA's revised regulations are intended to preserve FDA's ministerial role in listing patents (see 59 FR 50338 at 50349 and 68 FR 36676 at 36683 and 36687) and to also address ambiguous or overbroad use codes that could be a barrier to approval of a 505(b)(2) application or ANDA for uses that are not claimed by the listed patent (see § 314.53(b)(1), (c)(2)(ii)(P)(*3*), and (f)(1)). If an NDA holder provides a timely response to a patent listing dispute and a 505(b)(2) or ANDA applicant disagrees with the NDA holder's response to the patent listing dispute (or disagrees with the use code), the 505(b)(2) or ANDA applicant may submit a paragraph IV certification to challenge the method-of-use patent and assert a counterclaim in the context of an infringement action or pursue a declaratory judgment action, as appropriate, to obtain patent certainty (see section 505(c)(3)(D)(i) and (ii) and (j)(5)(C)(i) and (ii) of the FD&C Act).

We disagree, however, that the counterclaim procedure in section 505(c)(3)(D)(ii) and (j)(5)(C)(ii) of the FD&C Act obviates the need for an enhanced patent listing dispute procedure. Nothing in the FD&C Act precludes FDA from developing a procedure for patent listing disputes in light of our broad authority to issue regulations for the efficient enforcement of the FD&C Act. As the U.S. Supreme Court observed in *Caraco Pharm. Labs.,* ''the counterclaim cannot restore the smooth working of a statutory scheme thrown off kilter by an overly broad use code. At best, it permits the generic manufacturer to do what the scheme contemplates it should do—file an ANDA with a section viii statement—but only after expensive and time-consuming litigation. A fix is in order, but it must come from Congress or FDA'' (132 S.Ct. 1670 at 1689).

Finally, we note that comments recommending that FDA seek clarification or correction of patent information through other means do not describe an alternative to the approach we proposed. We believe that the modifications that we have made to the patent listing dispute procedure, discussed in Response 22, and our stepwise approach to evaluating whether FDA's revisions to this procedure and the regulations on submission of method-of-use patent information address the problem of overbroad and ambiguous use codes, adequately address the comments received on our proposal.

(Comment 24) Three comments assert that FDA's proposed deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent would be inconsistent with the Agency's longstanding ministerial role in patent-related matters. These comments suggest that FDA lacks the expertise to assess the adequacy of use codes and determine whether deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent is justified. A fourth comment suggests that FDA provide an administrative appeals process and Administrative Law Judge review where FDA reviews a proposed labeling carve-out for a 505(b)(2) application or ANDA with deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent. This comment also suggests that FDA avoid a ''mere ministerial approach.''

(Response 24) As noted in Response 23, we are not finalizing this proposal at this time. Accordingly, we do not need to address comments regarding specific aspects of implementation of this proposal in this final rule.

(Comment 25) One comment recommends that FDA require an NDA holder to respond to a request to confirm the accuracy or relevance of patent information in 15 days, rather than 30 days. The comment maintains that a 15-day timeframe is consistent with the regulatory timeframe to make corrections to an incomplete or otherwise inadequate submission of patent information (see § 314.53(c)(2)(ii)).

(Response 25) We decline to modify the regulation as requested. We believe that a period of 30 days from the date on which FDA sends the statement of dispute to the NDA holder provides an appropriate opportunity for the NDA holder to consider the statement of dispute and submit a response that addresses the requirements of § 314.53(f)(1)(i).

(Comment 26) Two comments recommend that FDA clarify that an NDA holder's amendment to the use code in response to a patent listing dispute will not be considered untimely filed patent information under §§ 314.50(i)(4) and 314.94(a)(12)(vi). One comment expresses concern that whether and how an NDA holder responds to a method-of-use patent listing dispute may affect the availability of a 30-month stay should the NDA holder subsequently file a patent infringement action in response to notice of a paragraph IV certification to the patent.

(Response 26) We agree that an NDA holder's amendment to its use code or related information on Form FDA 3542 in response to a patent listing dispute should not be considered untimely filed patent information if it is submitted within 30 days of FDA's request under § 314.53(f)(1)(i)(B) and contains the information required under § 314.53(f)(1)(i)(B)(*1*) or (*2*) (see §§ 314.50(i)(4)(i) and 314.94(a)(12)(vi)(A) (describing untimely filing of patent information ''except as provided in § 314.53(f)(1)'')). We note, however, that if an NDA holder responds to the patent listing dispute with an amendment to its use code more than 30 days after the date on which FDA sends the statement of dispute to the NDA holder, FDA will consider the amendment to be untimely filing of patent information because the submission does not comply with the requirements of § 314.53(f)(1).

The patent listing dispute procedure would not have an impact on the availability of a 30-month stay if other statutory and regulatory criteria are met (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act and § 314.107).

V.B.4.b. *Requests by NDA holder (§ 314.53(f)(2)).* We proposed to expressly require that if an NDA holder determines that a patent or patent claim (*e.g.,* a method-of-use claim) no longer meets the statutory requirements for listing, the NDA holder must promptly notify FDA to withdraw the patent or patent information and request that the patent or patent information be removed from the list (see proposed § 314.53(f)(2)(i) and section 505(b)(1) and (c)(2) of the FD&C Act). If an NDA holder is required by court order to amend patent information or withdraw a patent from the list, we proposed to require the NDA holder to submit a copy of the court order to the Orange Book Staff within 14 calendar days of the date on which the order was entered. We also proposed to codify our current practice of removing a patent or patent information from the Orange Book when the NDA holder has informed us that the patent no longer meets the statutory requirements for listing if there is no first applicant eligible for 180-day exclusivity or upon the expiration of the 180-day exclusivity period (see proposed § 314.53(f)(2)(i)). In addition, we proposed that if the term of the patent is extended under the patent term restoration provisions of 35 U.S.C. 156, the NDA holder must submit a correction to the patent expiration date on Form FDA 3542 within 30 calendar days of receipt of a certificate of extension or documentation of an extension of the term of the patent (see proposed § 314.53(f)(2)(ii) and 35 U.S.C. 156(e)(1) and (2)).

We proposed to require that corrections or changes to previously submitted patent information must be submitted on Form FDA 3542a or 3542,

as appropriate (see proposed § 314.53(f)(2)(iii)). However, we proposed to clarify that an NDA holder's withdrawal of a patent and request to remove a patent from the list is not required to be submitted on Form FDA 3542, but the request must specify the patent number, the application number, and each product(s) approved in the application to which the request applies (see proposed § 314.53(f)(2)(iv)).

In the following paragraphs, we discuss two comments on these proposed provisions. After considering these comments, we are making clarifying revisions to the description of the required amendment or supplement and the address to which the amendment or supplement must be submitted, and technical amendments described in sections V.B.2.c and V.P.3 We are also revising proposed § 314.53(f)(2)(i) to more precisely describe our practice of removing a patent or patent information from the list in response to an NDA holder's request if there is no first applicant eligible for 180-day exclusivity based on a paragraph IV certification to that patent or after the 180-day exclusivity period of a first applicant based on that patent has expired or has been extinguished.

(Comment 27) Two comments request that FDA clarify the implications of failing to timely amend patent information or withdraw a patent. One of the comments requests that FDA clarify the meaning of ''promptly notify FDA'' in proposed § 314.53(f)(2)(i), and explain whether the timeframe may differ based on the circumstances (*e.g.,* delay withdrawal of an original patent held invalid until the reissued patent has issued). The other comment suggests that if the NDA holder fails to timely notify FDA of a patent term extension or of a court order to amend patent information or withdraw a patent from the list, the patent should be considered untimely filed.

(Response 27) FDA is establishing regulatory timeframes for withdrawal or amendment of patent information and withdrawal of a patent to promote the NDA holder's timely compliance with obligations under the FD&C Act and applicable regulations. If the NDA holder determines that a patent or patent claim no longer meets the statutory requirements for listing, the NDA holder must ''promptly notify FDA'' to withdraw the patent or patent information or amend the patent information to ensure that pending 505(b)(2) applications or ANDAs that contain a patent certification to the amended or withdrawn patent or patent information are not inappropriately delayed if they are otherwise eligible for approval. An NDA holder's withdrawal or amendment of patent information or withdrawal of the patent within 14 days of the date on which the NDA holder determines that the patent or patent claim no longer meets the requirements for listing under section 505(b)(1) or (c)(2) of the FD&C Act would be considered ''prompt.'' If a court enters a final decision from which no appeal has been or can be taken that a patent is invalid, the NDA holder must promptly notify FDA to withdraw the patent and request that the patent be removed from the list irrespective of whether the NDA holder or patent owner is separately requesting a reissue of the patent.

We decline to modify the regulation to consider a patent untimely filed if the NDA holder fails to notify FDA of a court order to amend or withdraw patent information within 14 days because a court can enforce a failure to comply with its order. We also decline to modify the regulation to consider a patent untimely filed if the NDA holder fails to notify FDA of a patent term extension within 30 days because NDA holders have adequate incentive to inform FDA of any patent term extension. We require NDA holders to submit on Form FDA 3542 a correction to the expiration date of the listed patent if the term is extended under 35 U.S.C. 156(e) to ensure that prospective 505(b)(2) and ANDA applicants have timely notice of changes to the asserted patent coverage for a listed drug.

(Comment 28) One comment recommends that FDA clarify where an NDA holder should send a voluntary request to remove patent information from the list.

(Response 28) We agree. We are revising § 314.53(f)(2)(iv) to clarify that the NDA holder must submit an amendment to its NDA to the same addresses described in § 314.53(d)(4)(ii) to promptly notify FDA to withdraw a patent and request that FDA remove a patent from the list. We are also revising § 314.53(f)(2)(i) and (iii) to clarify that an NDA holder must submit a copy of a court order to amend patent information or withdraw a patent from the list in an amendment to its NDA that bears the identification described in § 314.53(d)(6) (''Time Sensitive Patent Information''). In addition, we are changing the address for submission of the amendment from the Orange Book Staff to the CDER Central Document Room, consistent with § 314.53(d)(4)(ii).

V.C. Patent Certification (§§ 314.50(i) and 314.94(a)(12))

V.C.1. Method-of-Use Patents (§§ 314.50(i)(1)(iii) and 314.94(a)(12)(iii))

We proposed to revise §§ 314.50(i)(1)(iii) and 314.94(a)(12)(iii) to clarify that a 505(b)(2) or ANDA applicant that is not seeking approval for a condition of use other than an indication (*e.g.,* a dosing regimen) that is covered by a method-of-use patent for the listed drug(s) relied upon or RLD, respectively, may submit a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the FD&C Act, instead of a patent certification with respect to any such method-of-use claims.

We received no comments regarding this proposed revision. We are finalizing proposed §§ 314.50(i)(1)(iii) and 314.94(a)(12)(iii) with technical amendments to reflect the claim-based approach to patent certification requirements for patents that include a method-of-use claim (*i.e.,* a 505(b)(2) or ANDA applicant may submit a statement with respect to one or more method-of-use claims and a paragraph IV certification with respect to the remaining patent claims). As revised, a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the FD&C Act may be submitted if the applicant is not seeking approval for ''an'' indication or other condition of use claimed by a method-of-use patent rather than ''any'' indications or other conditions of use claimed by the method-of-use patent (see §§ 314.50(i)(1)(iii) and 314.94(a)(12)(iii)).

We also are making technical amendments throughout part 314 to clarify that a 505(b)(2) or ANDA applicant may submit an appropriate patent certification *or statement* (see, *e.g.,* §§ 314.50(i)(1)(i)(A) through (C), (i)(5), (i)(6), (i)(6)(ii), (i)(6)(iii)(A)(*1*) and (*2*); 314.53(d)(3); and 314.94(a)(12)(i)(A) and (B), (a)(12)(vii) and (viii), (a)(12)(viii)(B), and (a)(12)(viii)(C)(*1*)(*i*) and (*ii*)).

V.C.2. Method-of-Manufacturing Patents (Deletion of §§ 314.50(i)(2) and 314.94(a)(12)(iv))

We proposed to remove §§ 314.50(i)(2) and 314.94(a)(12)(iv), which provide that an applicant is not required to make a certification with respect to any patent that claims only a method of manufacturing the drug product (method-of-manufacturing patent or process patent) for which the applicant is seeking approval. We proposed this deletion for clarity and consistency with the regulation that

prohibits an NDA holder from submitting information on a patent that only claims a method of manufacturing the drug product (see § 314.53(b)).

In the following paragraphs, we discuss a comment on this proposed deletion. After considering this comment, we are removing (and reserving) §§ 314.50(i)(2) and 314.94(a)(12)(iv).

(Comment 29) One comment recommends that FDA permit the listing of process patents that claim production of the active pharmaceutical ingredient in the approved drug product (*e.g.,* synthesis process or impurity reduction process).

(Response 29) We decline to adopt the suggestion provided in the comment. The FD&C Act requires an NDA applicant or holder to submit information on any patent that claims the drug or that claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug (see section 505(b)(1) and (c)(2) of the FD&C Act). A method-of-manufacturing patent or process patent does not meet the statutory requirement for listing because it does not claim an approved drug or an approved method of using the drug. We note, however, that a product-by-process patent is eligible for listing in the Orange Book because the invention claimed by the patent is, for example, the novel drug product and not the process used to make the product (see 68 FR 36676 at 36679 to 36680).

V.C.3. Licensing Agreement (§§ 314.50(i)(3) and 314.94(a)(12)(v))

We proposed to revise § 314.50(i)(3) regarding licensing agreements to remove the references to an ''immediate effective date'' and clarify that the patent owner with whom the applicant has a licensing agreement may consent to approval of the 505(b)(2) application (if otherwise justified) as of a specific date. We explained that this proposed revision did not alter the current requirements for a 505(b)(2) (or ANDA) applicant to submit a paragraph IV certification to a patent that claims the listed drug relied upon even though the applicant has a licensing agreement with the patent owner (see proposed §§ 314.50(i)(3) and 314.94(a)(12)(v)). We further explained that an applicant that has a licensing agreement with the patent owner would still be required to send notice of the paragraph IV certification to the NDA holder and each patent owner.

In the following paragraphs, we discuss a comment on this proposed revision. After considering this comment, we are making a clarifying revision and editorial corrections to § 314.50(i)(3) and conforming revisions to § 314.94(a)(12)(v).

(Comment 30) One comment requests that FDA revise § 314.50(i)(3) to apply to an ''agreement'' between a 505(b)(2) applicant and the patent owner(s), rather than restrict the provision to a ''licensing agreement.'' The comment maintains that other forms of agreement (*e.g.,* a covenant not to sue) should not be treated differently for purposes of determining the earliest date agreed upon by the applicant and relevant patent owner(s) for approving an application. The comment also recommends that FDA amend § 314.94(a)(12)(v) to expressly describe consent to approval as of a specific date because the provision also should apply to ANDAs.

(Response 30) We decline to modify § 314.50(i)(3) to broadly refer to an agreement between a 505(b)(2) applicant and the patent owner. Licensing agreements are described in section 505(b)(1) and (c)(2) of the FD&C Act, which refer to a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. It accords with the statute for a 505(b)(2) applicant to submit a paragraph IV certification based on a licensing agreement with the patent owner, and for the patent owner to consent to approval of the 505(b)(2) application as of a specific date (if the 505(b)(2) application is otherwise eligible for approval). However, it is unclear whether other types of agreements (*e.g.,* a covenant not to sue) would necessarily be consistent with a paragraph IV certification that the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the proposed product for which the 505(b)(2) application (or ANDA) is submitted. The FD&C Act does not contemplate FDA enforcement of private agreements between a 505(b)(2) (or ANDA) applicant and a patent owner that are unrelated to the statutory and regulatory requirements for approval.

As a practical matter, it is unnecessary to broaden this provision to describe other circumstances in which a patent owner may consent to approval as of a specific date. If a 505(b)(2) applicant submits a paragraph IV certification and the patent owner provides a covenant not to sue, then the patent owner would not initiate patent infringement litigation within the 45-day period and there would be no 30-month stay of approval. If a 505(b)(2) applicant changes a previously submitted certification or statement to a paragraph IV certification, the patent owner and NDA holder for the listed drug relied upon may waive their opportunity to file a patent infringement action within the 45-day period (see § 314.107(f)(3)).

We agree that the regulations should expressly provide that if an ANDA applicant has a licensing agreement with a patent owner, the patent owner may consent to approval of the ANDA as of a specific date (if the ANDA is otherwise eligible for approval). We are revising § 314.94(a)(12)(v) to describe the requirements for a written statement from the patent owner that has a licensing agreement with the applicant and consents to approval of the ANDA as of a specific date. Agreements between an ANDA applicant and a brand name drug company that must be filed with the Assistant Attorney General and the FTC are described in section 1112 of the MMA.

We also are revising §§ 314.50(i)(3) and 314.94(a)(12)(v) to clarify that the 505(b)(2) application or ANDA will be approved based on consent to approval as of a specific date only if the 505(b)(2) application or ANDA is ''otherwise eligible for approval'' rather than ''otherwise justified.''

V.D. Notice of Paragraph IV Certification (§§ 314.52 and 314.95)

V.D.1. Timing of Notice

V.D.1.a. *Date before which notice may not be given.* We proposed to revise our regulations to clearly delineate the two limitations on the timeframe within which notice of a paragraph IV certification to a listed patent must be provided to the NDA holder and each patent owner: The date before which notice must not be given and, as discussed in section V.D.1.b, the date by which notice must be given.

We proposed to codify our longstanding policy that notice of a paragraph IV certification may not be sent by a 505(b)(2) or ANDA applicant unless and until we have notified the applicant that its application has been filed or received, as appropriate (see proposed §§ 314.52(b)(1) and 314.95(b)(1)). We proposed that any notice sent by a 505(b)(2) or ANDA applicant before the receipt of an acknowledgment letter or paragraph IV acknowledgment letter is invalid, and thus does not trigger either the 45-day period in which the NDA holder and each patent owner may initiate a patent

infringement action and obtain a 30-month stay or the beginning of any related 30-month period. We proposed that an applicant that prematurely sends notice of a paragraph IV certification would be required to resend notice within the required timeframe after the 505(b)(2) application or ANDA has been filed or received, respectively, to satisfy the notice requirement of the FD&C Act and, in the case of a first applicant, to qualify for 180-day exclusivity (see proposed §§ 314.52(b)(2) and 314.95(b)(2)).

We proposed to clarify that if a 505(b)(2) or ANDA applicant submits an amendment containing a paragraph IV certification before the filing or receipt of the 505(b)(2) application or ANDA, respectively, the applicant would be required to wait until it has received an acknowledgment letter or a paragraph IV acknowledgment letter before sending notice of its paragraph IV certification to the NDA holder and each patent owner (see proposed §§ 314.52(b) and (d)(2) and 314.95(b) and (d)(2)).

With respect to patents that are listed in the Orange Book after submission of an ANDA, we proposed that any notice of paragraph IV certification would be invalid and would not be considered to comply with the notice requirement of the FD&C Act if it is sent before the first working day after the day the patent is listed in the Orange Book (see proposed §§ 314.94(a)(12)(viii)(C)(*1*)(*ii*) and 314.95(b)(2)). We proposed that the term ''working day'' would have the meaning provided in 21 CFR 1.377 (''any day from Monday through Friday, excluding Federal holidays''). We explained that this proposal is intended to discourage ANDA applicants from submitting a paragraph IV certification and sending notice to the NDA holder and each patent owner every day during the 30-day period after issuance of a patent that could be listed for the RLD in an effort to qualify as a first applicant eligible for 180-day exclusivity if such patent ultimately is listed for the RLD in the Orange Book. We also noted that this proposed requirement would ensure that all ANDA applicants (irrespective of time zone) have a reasonable opportunity to be first to certify to a newly listed patent.

In the following paragraphs, we discuss several comments on our proposed regulations regarding the date before which notice of paragraph IV certification must not be given. After considering these comments, we are revising § 314.52(b)(2) to provide that a 505(b)(2) applicant must send notice of a paragraph IV certification on or after the date of filing of the 505(b)(2) application described in § 314.101(a)(2) or (3), as applicable, rather than on or after the date it receives a paragraph IV acknowledgment letter. We are revising proposed § 314.95(b)(2) to delete the reference to an ''acknowledgment letter'' because an ANDA applicant will now receive a ''paragraph IV acknowledgment letter'' if it amends its ANDA to add a paragraph IV certification before the ANDA is received (see section V.A.1).

(Comment 31) One comment asserts that the statutory terms ''submits'' and ''files'' in section 505(j)(2)(B)(ii)(I) and (II) of the FD&C Act, respectively, indicate that an ANDA applicant may send notice of a paragraph IV certification at the time of submission of an amendment to an ANDA containing a paragraph IV certification, even if the ANDA has not yet been ''filed'' (*i.e.,* ''received'' under § 314.101(b)). The comment suggests that ANDA applicants that submit an amendment containing the first paragraph IV certification to a patent listed for the RLD are concerned that they may risk eligibility for 180-day exclusivity if they do not send notice at the time of submission of the amendment, even though the ANDA has not been received under § 314.101(b). The comment proposes that FDA allow ANDA applicants to ''change'' rather than ''amend'' their patent certification in an amendment prior to filing, and consider the date of the ''change'' for purposes of determining eligibility for 180-day exclusivity.

(Response 31) We disagree with the comment's interpretation of section 505(j)(2)(B)(ii)(II) of the FD&C Act, and decline to adopt the comment's proposed revision to the regulations governing submission of a paragraph IV certification prior to receipt of the ANDA.

As a preliminary matter, we note that the requirement that an ANDA applicant must wait until its ANDA has been received before sending notice of a paragraph IV certification ensures that the NDA holder and patent owner do not needlessly expend resources to initiate litigation with respect to an ANDA that is incomplete and therefore may not be reviewed by the Agency (see ''Abbreviated New Drug Application Regulations,'' 54 FR 28872 at 28887, July 10, 1989; see also 59 FR 50338 at 50349 to 50350). This reflects the Agency's view that Congress did not intend for incomplete ANDA submissions to have the potential to trigger legal action by an NDA holder or patent owner (see 54 FR 28872 at 28887; see also *Allergan, Inc.* v. *Actavis, Inc.,* 2014 WL 7336692 at *12 (E.D. Tex. 2014) (finding that the act of infringement created by 35 U.S.C. 271(e)(2) requires that the ANDA has been received by FDA, not merely transmitted to FDA). Accordingly, our existing regulations require that an ANDA applicant's notice of a paragraph IV certification must include a statement that FDA has received the ANDA (see § 314.95(c)(1)).

The requirement that notice of a paragraph IV certification only be sent after FDA has received the ANDA was ratified by the MMA, which established a 20-day period for sending notice of a paragraph IV certification that runs from the date of the postmark on the notice with which FDA informs the applicant that the ANDA has been filed (*i.e.,* received under § 314.101(b)) (see section 505(j)(2)(B)(ii)(I) of the FD&C Act and section V.D.1.b). The MMA also requires that an ANDA applicant send notice of a paragraph IV certification submitted in an amendment or supplement to the ANDA at the time of submission of the amendment or supplement, regardless of whether the applicant already has given notice with respect to another paragraph IV certification contained in the ANDA or in an amendment or supplement to the ANDA (see section 505(j)(2)(B)(ii)(II) of the FD&C Act). Consistent with the framework established by section 505(j)(2)(B)(ii) of the FD&C Act, FDA interprets section 505(j)(2)(B)(ii)(II) of the FD&C Act to apply only to an amendment to the ANDA that is submitted after the Agency has received the ANDA (see *SB Pharmco Puerto Rico, Inc.* v. *Mutual Pharmaceutical Co.,* 552 F. Supp. 2d 500, 510 (E.D. Pa.), *appeal dismissed,* 2008 U.S. App. LEXIS 27672 (Fed. Cir. 2008) (upholding FDA's interpretation of section 505(j)(2)(B)(ii)(II) of the FD&C Act and finding that notice of a paragraph IV certification sent at the time of submission of an amendment to an ANDA that had not yet been received ''was not valid or timely''). Thus, we disagree with the comment's suggestion that an ANDA applicant can submit an amendment containing a paragraph IV certification before the ANDA is received and immediately send notice of the paragraph IV certification. If an ANDA applicant submits an amendment containing a paragraph IV certification before it has received a paragraph IV acknowledgment letter advising that the ANDA has been received for substantive review, the applicant is required to send notice of its paragraph IV certification within 20 days after the date of the postmark on the paragraph IV acknowledgment letter.

Based on the Agency's interpretation of the statute, it is unnecessary to use the terminology suggested in the

comment to describe an amendment that contains a paragraph IV certification to a newly listed patent or that changes a previously submitted patent certification or statement to a paragraph IV certification and is submitted before receipt of the ANDA.

The relevant date for determining eligibility for 180-day exclusivity based upon submission of a paragraph IV certification contained in an amendment is the date of submission of the amendment. We are revising § 314.95(d)(2) to clarify that if an ANDA applicant's notice of paragraph IV certification is timely provided in accordance with § 314.95(b)(2) and the applicant has not submitted a previous paragraph IV certification, FDA will base its determination of whether the applicant is a first applicant on the date of submission of the amendment containing the paragraph IV certification.

(Comment 32) One comment accepts FDA's ''settled administrative practice'' that a 505(b)(2) or ANDA applicant may not send notice of paragraph IV certification until the application is accepted for review, but contends that FDA may not condition a 505(b)(2) applicant's ability to send notice on its prior receipt of a paragraph IV acknowledgment letter that would be sent up to 14 days after the 505(b)(2) application is accepted for review (filed). The comment maintains that the benefits of this approach have not been shown to outweigh the costs of a potential 2-week delay in approval of a 505(b)(2) application, and that the proposal is inconsistent with the statute. Another comment recommends that FDA send a paragraph IV acknowledgment letter to a 505(b)(2) applicant via email on the date on which the 505(b)(2) application is filed to eliminate the disparity between the dates on which paragraph IV acknowledgment letters are sent to 505(b)(2) and ANDA applicants. A third comment requests that FDA clarify when an ANDA applicant can send notice if the paragraph IV acknowledgment letter is not received on day 60.

(Response 32) We agree that there should not be a delay of approximately 2 weeks between the date on which a 505(b)(2) application is filed and the date on or after which a 505(b)(2) applicant must send notice of a paragraph IV certification to the NDA holder and each patent owner. We are revising proposed § 314.52(b)(1) and (2) to provide that a 505(b)(2) applicant must send notice of a paragraph IV certification on or after the date of filing of the 505(b)(2) application described in § 314.101(a)(2) or (3), as applicable, rather than on or after the date it receives a paragraph IV acknowledgment letter, and we are making conforming revisions to § 314.52(d)(1) and (2). This revised approach ensures that notice of a paragraph IV certification will not be sent before the Agency has filed the relevant 505(b)(2) application, and avoids a delay of up to 2 weeks in the potential initiation of patent infringement litigation by an NDA holder or patent owner and any corresponding 30-month stay of approval of the 505(b)(2) application.

FDA determines whether a 505(b)(2) application may be filed within 60 days after FDA is in receipt of the 505(b)(2) application (see § 314.101(a)(1)). If the 505(b)(2) applicant does not receive a refusal to file letter on or before day 60, the 505(b)(2) application is deemed filed. If FDA refuses to file the 505(b)(2) application and the 505(b)(2) application is filed over protest or resubmitted, then the date of filing described in § 314.101(a)(3) applies. We are requiring that a 505(b)(2) applicant send notice of a paragraph IV certification on or after the date of filing of the 505(b)(2) application, but not later than 20 days after the date of the postmark on the paragraph IV acknowledgment letter (see § 314.52(b)(1)). The ''paragraph IV acknowledgment letter'' for a 505(b)(2) application is the filing communication that generally is sent to the 505(b)(2) applicant not later than 14 calendar days after the 60-day filing date (sometimes referred to as the ''74 day letter'') (see section V.A.1). The ''date of the postmark'' for a paragraph IV acknowledgment letter for a 505(b)(2) application is considered to be four calendar days after the date on which the letter is signed by the signatory authority (generally the Division Director or designee in the OND review division). Accordingly, this revision to our regulations implements the statutory requirement that notice be sent within 20 days of the postmark on the filing communication while preserving the principle that notice must not be sent before a 505(b)(2) application is filed.

We are maintaining the requirement that an ANDA applicant must send notice of a paragraph IV certification on or after the date it receives a paragraph IV acknowledgment letter because FDA intends to electronically transmit the letter to the ANDA applicant on the date on which the ANDA is received under § 314.101(b). Accordingly, in contrast to the interval of up to 14 days for 505(b)(2) applications, there is no interval between the date on which the ANDA is received under § 314.101(b) and the date on which an ANDA applicant receives a paragraph IV acknowledgment letter (see section V.A.6). An ANDA applicant can send notice of a paragraph IV certification submitted in an original ANDA or submitted in an amendment to an ANDA that has not yet been received on or after the date the ANDA applicant receives a paragraph IV acknowledgment letter.

(Comment 33) One comment asserts that the proposed requirement that a paragraph IV certification must not be submitted earlier than the first working day after the day the patent or patent claim is listed in the Orange Book would conflict with the statute and prevent ANDA applicants from submitting a paragraph IV certification to a newly listed patent at the first lawful opportunity. Another comment maintains that the proposed requirement for submission of a paragraph IV certification to a newly listed patent may result in multiple ANDA applicants becoming eligible for 180-day exclusivity and thus would dilute the value of 180-day exclusivity.

(Response 33) We believe that our approach to patent certification requirements for newly listed patents is consistent with the statute and provides a reasonable opportunity for ANDA applicants to compete to have the first substantially complete ANDA that contains a paragraph IV certification to a listed patent for the RLD.

The requirement that an ANDA applicant must not submit a paragraph IV certification earlier than the first working day after the day the patent or patent claim is listed in the Orange Book reflects FDA's determination that selecting the first working day after the day on which the patent information is published creates a level playing field for all ANDA applicants (see §§ 314.94(a)(12)(viii)(C)(*1*)(*ii*) and 314.95(b)(2)). One court has determined, in the absence of a regulation to the contrary, that ''reality matters'' if a patent has been submitted to FDA, and an ANDA applicant can submit a paragraph IV certification even if the patent is not yet listed in the Orange Book (see *Teva Pharms., USA, Inc.* v. *Leavitt,* 548 F.3d 103, 105 (D.C. Cir. 2008)). However, FDA has determined that permitting serial submissions of amendments and multiple notices of paragraph IV certifications is overly burdensome to FDA and NDA holders. Such a practice makes it difficult to determine which paragraph IV certification and notice of paragraph IV certification is valid. Our decision to

level the playing field for paragraph IV certifications in this manner is consistent with our authority to establish rules for the efficient enforcement of the FD&C Act (see section 701(a) of the FD&C Act).

We are not persuaded by the comment's assertion that leveling the playing field for ANDA applicants will dilute the value of 180-day exclusivity. For example, FDA continues to receive multiple ANDAs on the day that 4 years of a 5-year exclusivity period under section 505(j)(5)(F)(ii) of the FD&C Act has expired (the first day that ANDAs containing a paragraph IV certification are permitted to be submitted) even though many of these ANDAs will likely share eligibility for 180-day exclusivity.

(Comment 34) One comment supports the proposed requirement that a paragraph IV certification must not be submitted earlier than the first working day after the day the patent or patent claim is listed in the Orange Book, but recommends that FDA establish a time after which patent information listed in the Orange Book will be deemed to have been published the next day. Another comment suggests that FDA instantaneously notify ANDA applicants when a patent is listed for the RLD after ANDA submission to provide an equal opportunity for timely submission of an appropriate patent certification or statement to the pending ANDA and, if applicable, notice of paragraph IV certification.

(Response 34) We decline to adopt the suggestions provided in the comments. FDA generally posts daily electronic updates to the Orange Book in the afternoon (Eastern Standard Time); however, we are not establishing a specific time by which FDA will update the Orange Book to preserve flexibility in the event of technical difficulties. Applicants will have an equal opportunity for timely submission of an appropriate patent certification or statement for a newly listed patent or patent claim because FDA will make this information publicly available through the Orange Book. Although we decline to undertake the burden of notifying individual ANDA applicants when a patent or patent claim for the RLD is newly listed in the Orange Book, we are committed to facilitating public access to the Orange Book through efficient means (see, *e.g.,* the ''Orange Book Express'' mobile application launched on November 9, 2015).

V.D.1.b. *Date by which notice must be given.* We proposed to establish a regulation that would implement section 505(b)(3)(B) and (j)(2)(B)(ii) of the FD&C Act by providing that an applicant must send notice of a paragraph IV certification contained in a 505(b)(2) application or ANDA not later than 20 days after the date of the ''postmark'' on the acknowledgment letter or paragraph IV acknowledgment letter (see proposed §§ 314.52(b)(1) and 314.95(b)(1) and section 505(b)(3)(B)(i) and (j)(2)(B)(ii)(I) of the FD&C Act). We proposed a definition of the term ''postmark'' and, as applied to paragraph IV acknowledgment letters for 505(b)(2) applications, an alternate proposed interpretation of the term ''postmark'' to reflect current practice regarding the mailing of filing communications (see section V.A.1). We also proposed to specify the method of calculating the 20-day period for providing notice of a paragraph IV certification (see proposed §§ 314.52(b)(1) and 314.95(b)(1)).

We proposed that an applicant must send notice of a paragraph IV certification contained in an amendment to a 505(b)(2) application or ANDA that has been filed or received for substantive review, respectively, or in a supplement to an approved 505(b)(2) application or ANDA at the same time that the amendment or supplement is submitted to FDA (see proposed §§ 314.52(d)(1) and 314.95(d)(1) and section 505(b)(3)(B)(ii) and (j)(2)(B)(ii)(II) of the FD&C Act). We proposed that notice of a paragraph IV certification in an amendment or supplement must be provided regardless of whether the applicant has already given notice with respect to another paragraph IV certification contained in the 505(b)(2) application or ANDA or in an amendment or supplement to the 505(b)(2) application or ANDA (see proposed §§ 314.52(d)(1) and 314.95(d)(1) and section 505(b)(3)(B)(ii) and (j)(2)(B)(ii)(II) of the FD&C Act).

We proposed to require an applicant that submits an amendment or supplement to a 505(b)(2) application or ANDA that seeks approval for a different strength of the drug product and contains a paragraph IV certification adhere to the timing requirements for notice in §§ 314.52(d)(1) or (2) and 314.95(d)(1) or (2), respectively, based on whether the 505(b)(2) application has been filed or the ANDA has been received (see proposed §§ 314.52(d)(3) and 314.95(d)(3)).

We did not receive any other comments on proposed §§ 314.52(b)(1), (d)(1) and (2), and 314.95(b)(1), (d)(1) and (2). We are finalizing proposed § 314.52(b)(1) and (2) and (d)(1) and (2) with the revisions discussed in Response 32. We are finalizing proposed § 314.95(b)(1) and (d)(2) with clarifying revisions to consistently refer to ''a paragraph IV acknowledgment letter'' because these provisions refer to an ANDA that contains a paragraph IV certification before the ANDA is received and thus FDA will send the ANDA applicant a paragraph IV acknowledgment letter. We also are making the clarifying revision to proposed § 314.95(d)(2) discussed in Response 31. We are finalizing proposed § 314.95(d)(1) with a clarifying revision to add the phrase ''or an acknowledgment letter'' because an applicant may amend or supplement its ANDA to include a paragraph IV certification irrespective of whether the ANDA contained a paragraph IV certification at the time of receipt. We also are making the technical amendment to § 314.95(d)(1) described in section V.P.1.

V.D.2. Contents of Notice

We proposed that a 505(b)(2) or ANDA applicant's notice of a paragraph IV certification must include, among other things: (1) A statement that data from any required bioavailability or bioequivalence studies have been submitted; (2) a statement that the applicant has received an acknowledgment letter or a paragraph IV acknowledgment letter for its 505(b)(2) application or ANDA; (3) the patent number and expiration date of each patent listed in the Orange Book that is the subject of the paragraph IV certification; and (4) an offer of confidential access, if the applicant alleges that the patent will not be infringed and may later decide to file a civil action for declaratory judgment in accordance with section 505(c)(3)(D) and (j)(5)(C) of the FD&C Act) (see proposed §§ 314.52(c) and 314.95(c)). We also proposed to require the 505(b)(2) or ANDA applicant to cite section 505(b)(3)(D) and (j)(2)(B)(iv) of the FD&C Act, respectively, as amended by the MMA, in the notice of paragraph IV certification (see proposed §§ 314.52(c) and 314.95(c)). In the proposed rule, we explained that the Agency assesses neither the adequacy of the contents of a 505(b)(2) or ANDA applicant's notice of paragraph IV certification nor the applicant's stated basis for certifying that a listed patent is invalid, unenforceable, or will not be infringed by its proposed drug product.

In the following paragraphs, we discuss two comments on the proposed requirements for the content of a notice of paragraph IV certification. After considering these comments, we are not finalizing proposed § 314.52(c)(3) and we are making conforming editorial changes to the numbering of subsequent paragraphs in § 314.52(c). We are

revising proposed § 314.95(c)(3) to omit the reference to an ''acknowledgment letter'' and require that the ANDA applicant include a statement that the applicant has received the paragraph IV acknowledgment letter for the ANDA. We are making a grammatical correction to the introductory text of §§ 314.52(c) and 314.95(c) to provide that the notice must include, but is not limited to, the information described in §§ 314.52(c)(1) through (8) and 314.95(c)(1) through (9). We are finalizing the remaining provisions of proposed §§ 314.52(c) and 314.95(c) without change, except for a revision to proposed §§ 314.52(c)(8) and 314.95(c)(8) to clarify that an offer of confidential access must be provided by an applicant that seeks to preserve the option to file a civil action for declaratory judgment in accordance with section 505(c)(3)(D) or (j)(5)(C) of the FD&C Act.

(Comment 35) One comment asserts that FDA lacks authority to require a 505(b)(2) or ANDA applicant to include, in any notice of paragraph IV certification, a statement that the applicant has received an acknowledgment letter or a paragraph IV acknowledgment letter because section 505(b)(3)(D) and (j)(2)(B)(iv) of the FD&C Act does not expressly require such a statement.

(Response 35) We disagree. FDA has the authority to establish regulations regarding the contents of notice of a paragraph IV certification to support the efficient enforcement of the FD&C Act (see section 701(a) of the FD&C Act). The FD&C Act requires that a notice of paragraph IV certification must state that the 505(b)(2) application or ANDA containing the certification ''has been submitted'' (see section 505(b)(3)(D)(i) and (j)(2)(B)(iv)(I) of the FD&C Act). As discussed in Response 31, it is the Agency's longstanding policy that notice of a paragraph IV certification may not be sent unless and until we have notified the applicant that its 505(b)(2) application has been filed or its ANDA has been received because premature notice could result in lawsuits over applications that FDA refuses to file or receive and thus no longer are pending. Accordingly, our existing regulations require that a 505(b)(2) or ANDA applicant's notice of a paragraph IV certification must include a statement that FDA has filed the NDA (in the case of a 505(b)(2) application) or has received the ANDA (see §§ 314.52(c)(1) and 314.95(c)(1)). To help ensure that notices of paragraph IV certifications are not sent prematurely, we also are requiring that an ANDA applicant's notice of paragraph IV certification include a statement that the applicant has received the paragraph IV acknowledgment letter for the ANDA (see § 314.95(c)(3)). We are revising proposed § 314.95(c)(3) to delete the reference to an ''acknowledgment letter'' because an ANDA applicant will now receive a ''paragraph IV acknowledgment letter'' if the ANDA contains a paragraph IV certification at any time before the ANDA is received (see section V.A.1).

With respect to a 505(b)(2) application, we are maintaining the requirement that a 505(b)(2) applicant's notice of a paragraph IV certification must include a statement that FDA has filed the NDA (see § 314.52(c)(1)). However, we are not requiring the 505(b)(2) applicant to include a statement that it has received a paragraph IV acknowledgment letter because we are revising our regulations to provide that a 505(b)(2) applicant must send notice of a paragraph IV certification on or after the date of filing of the 505(b)(2) application described in § 314.101(a)(2) or (3), as applicable, rather than on or after the date the applicant receives a paragraph IV acknowledgment letter (see § 314.52(b)(1) and Response 32).

(Comment 36) One comment requests that FDA revise the regulations to enable any recipient of notice of paragraph IV certification to request that FDA confirm the adequacy of notice with respect to statutory and regulatory requirements (other than the factual and legal basis for the paragraph IV certification). This comment recommends that FDA provide that inadequate notice is invalid and does not trigger the 45-day period described in section 505(c)(3)(C) or (j)(5)(B)(iii) of the FD&C Act. Another comment recommends that FDA provide an additional time period in which a 505(b)(2) or ANDA applicant can correct a deficient notice of paragraph IV certification that would extend the time for a patent holder under its duties or obligations.

(Response 36) We decline to revise the regulations to provide for a ministerial review of notice of a paragraph IV certification to evaluate compliance with the statutory and regulatory requirements. A 505(b)(2) or ANDA applicant is required to submit an amendment to its 505(b)(2) application or ANDA certifying, among other things, that the notice of paragraph IV certification met the content requirements under §§ 314.52(c) or 314.95(c), respectively (see §§ 314.52(b)(3) or 314.95(b)(3)). The regulations also provide that a copy of the notice of paragraph IV certification does not need to be submitted to FDA (see §§ 314.52(b)(3) or 314.95(b)(3)). Given the clarifying revisions to the regulations to enhance compliance with the requirements for notice of a paragraph IV certification and the administrative burden that would be associated with a ministerial review of a notice of paragraph IV certification, we do not believe that such review is warranted. The second comment does not clearly describe the requested action or provide adequate support for any proposed change. We note, however, that an applicant may amend its 505(b)(2) application or ANDA with a written statement that a later date should be used as the first day of the 45-day period provided in section 505(c)(3)(C) or (j)(5)(B)(iii) of the FD&C Act (see §§ 314.52(f) and 314.95(f)).

V.D.3. Documentation of Timely Sending and Receipt of Notice

V.D.3.a. *Acceptable methods of sending notice of paragraph IV certification.* We proposed to expand the list of acceptable delivery methods that 505(b)(2) and ANDA applicants may use to send notice of paragraph IV certification to the NDA holder and each patent owner by permitting a 505(b)(2) or ANDA applicant to use a ''designated delivery service'' (see proposed §§ 314.52(a) and 314.95(a)). We proposed to define a ''designated delivery service'' to mean a delivery service provided by a trade or business that FDA determines: (1) Is available to the general public throughout the United States; (2) records electronically to its database, kept in the regular course of its business, or marks on the cover in which any item referred to in this section is to be delivered, the date on which the item was given to the trade or business for delivery; and (3) provides overnight or 2-day delivery service throughout the United States (see §§ 314.52(g)(1) and 314.95(g)(1)). We proposed to periodically issue guidance describing designated delivery services that meet the regulatory criteria (see proposed §§ 314.52(g)(2) and 314.95(g)(2)). We also proposed to clarify that a 505(b)(2) or ANDA applicant may send notice of paragraph IV certification by an alternative method (*i.e.,* a method other than registered or certified mail, return receipt requested, or a designated delivery service) only if FDA has agreed in advance that the method will produce an acceptable form of documentation (see proposed §§ 314.52(a)(4) and (e) and 314.95(a)(4) and (e)).

In the following paragraphs, we discuss a comment on these proposed provisions. After considering this comment, we are finalizing proposed

§§ 314.52(a) and (g)(1) and 314.95(a) and (g)(1) without change, except for a technical amendment to add ''505(b)(2)'' before ''applicant'' in § 314.52(a) for clarity. We are revising §§ 314.52(g)(2) and 314.95(g)(2) to clarify that FDA may periodically issue guidance regarding designated delivery services.

(Comment 37) One comment requests that FDA clarify whether a 505(b)(2) or ANDA applicant may use a delivery service that appears to satisfy the criteria in §§ 314.52(g)(1) and 314.95(g)(1) even if the delivery service has not been identified by FDA in periodic guidance.

(Response 37) At this time, FDA does not intend to identify specific designated delivery services in guidance. A 505(b)(2) or ANDA applicant that sends notice of a paragraph IV certification may use a delivery service that satisfies the regulatory criteria in §§ 314.52(g)(1) or 314.95(g)(1), as applicable, without FDA's prior approval. For purposes of the definition of ''designated delivery service,'' FDA is clarifying that ''United States'' means the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico, but not the Territories. This approach acknowledges that some delivery services may not routinely provide overnight or 2-day delivery services to each of the Territories of the United States. If a 505(b)(2) or ANDA applicant is required to send notice of a paragraph IV certification to an NDA holder or patent owner (or its representative) that resides in a Territory of the United States or outside the United States, the applicant should ensure that the designated delivery service provides service to the area or request permission to use an alternate method of delivery.

We are revising §§ 314.52(g)(2) and 314.95(g)(2) to clarify that FDA may periodically issue guidance regarding designated delivery services. We note that a 505(b)(2) or ANDA applicant may send notice of a paragraph IV certification by an alternate method that does not meet the criteria in §§ 314.52(g)(1) or 314.95(g)(1) only if the applicant has obtained FDA's agreement in advance (see §§ 314.52(a)(4) and 314.95(a)(4)).

V.D.3.b. *Amendment documenting timely sending and confirmation of receipt of notice of paragraph IV certification.* We proposed to revise §§ 314.52(e) and 314.95(e) to clarify the requirements for submission of an amendment to a 505(b)(2) application or ANDA, respectively, containing documentation of timely sending of notice of paragraph IV certification and confirmation of receipt of same by the NDA holder and each patent owner.

We proposed that an applicant must amend its 505(b)(2) application or ANDA at the time that it provides notice of a paragraph IV certification with a statement certifying that notice has been provided to the NDA holder and each patent owner as required by §§ 314.52(a) and 314.95(a) and met the content requirements described in §§ 314.52(c) and 314.95(c) (see proposed §§ 314.52(b)(3) and 314.95(b)(3)). We also proposed to clarify that a copy of the notice of paragraph IV certification itself does not need to be submitted to FDA in the amendment (see proposed §§ 314.52(b)(3) and 314.95(b)(3)).

We proposed that an applicant must amend its 505(b)(2) application or ANDA with documentation that the notice of paragraph IV certification was sent on a date that complies with the timeframe required by § 314.52(b) or (d) or § 314.95(b) or (d), as applicable (see proposed §§ 314.52(e) and 314.95(e) and section 505(b)(3)(B) and (j)(2)(B)(ii) of the FD&C Act). For administrative efficiency, we proposed that a 505(b)(2) or ANDA applicant can submit a single amendment that contains documentation of timely sending of the notice(s) of paragraph IV certification and receipt of the notice(s) by each person provided the notice. We proposed that the amendment must be submitted within 30 days after the last date on which notice was received by a person described in § 314.52(a) or § 314.95(a), respectively (see proposed §§ 314.52(e) and 314.95(e)). We also proposed to clarify the types of documentation of timely sending and receipt of notice of paragraph IV certification that can satisfy the regulatory requirements (see proposed §§ 314.52(e) and 314.95(e)).

In addition, we proposed to require that ANDA applicants include in their amendment a dated printout of the Orange Book entry for the RLD that includes the patent that is the subject of the notice of paragraph IV certification. This proposed requirement would ensure that a paragraph IV certification that may qualify an ANDA applicant for 180-day exclusivity is submitted only for a listed patent and is not sent before the first working day after the day the patent is listed in the Orange Book (see proposed §§ 314.95(b)(2) and 314.94(a)(12)(viii)(C)(*1*)(*ii*)).

We did not receive any comments on these proposed revisions. However, for administrative efficiency, the Agency has revised §§ 314.52(b)(3) and 314.95(b)(3) to remove the requirement for a 505(b)(2) or ANDA applicant to submit an amendment at the time it sends notice of paragraph IV certification. Instead, the 505(b)(2) or ANDA applicant may submit a single amendment that contains the statements required by §§ 314.52(b)(3) and 314.95(b)(3) and documentation of timely sending and receipt of notice of paragraph IV certification if the amendment contains all of the information required by §§ 314.52(b)(3) and (e) and 314.95(b)(3) and (e) and is submitted within 30 days of the date on which the last notice was received.

V.E. Amended Patent Certifications (§§ 314.50(i)(6) and 314.94(a)(12)(viii))

We proposed to revise the introductory text of § 314.94(a)(12)(viii) to remove the provision that restricts an ANDA applicant from changing a paragraph IV certification to a paragraph III certification in certain circumstances. We also proposed to revise §§ 314.50(i)(6) and 314.94(a)(12)(viii) to require that a 505(b)(2) or ANDA applicant submit an amended patent certification as an amendment to its pending application (including a supplemental 505(b)(2) application or supplemental ANDA) and not by letter. We received no comments, and we are finalizing these proposed revisions to §§ 314.50(i)(6) and 314.94(a)(12)(viii) without change, except for the technical amendments described in sections V.P.2 and V.P.6.

V.E.1. Amended Patent Certifications After a Finding of Infringement

We proposed to amend §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A) to reflect changes to the FD&C Act made by the MMA that clarify the requirements for a 505(b)(2) or ANDA applicant to amend its paragraph IV certification after a judicial finding of patent infringement (see section 505(c)(3)(C)(ii)(II) and (j)(5)(B)(iii)(II)(bb) of the FD&C Act). We proposed to require that a 505(b)(2) and ANDA applicant submit an amendment to change its paragraph IV certification to a paragraph III certification or, if appropriate, to a statement under section 505(b)(2)(B) or (j)(2)(A)(viii) of the FD&C Act if a court enters a final decision from which no appeal has been or can be taken that the patent at issue is valid and has been infringed (see proposed §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A)). We proposed to apply this requirement irrespective of whether the patent infringement action was brought within 45 days of receipt of the notice of paragraph IV certification because a 505(b)(2) or ANDA applicant can no longer lawfully maintain a paragraph IV certification after the final court decision.

We also proposed to require a 505(b)(2) or ANDA applicant to submit an amendment to change its paragraph IV certification to a paragraph III certification or, if appropriate, to a statement under section 505(b)(2)(B) or (j)(2)(A)(viii) of the FD&C Act if a court signs a settlement order, or consent decree in the action that includes a finding that the patent is infringed, unless the final decision, settlement order or consent decree also finds the patent to be invalid (see proposed §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A)). We noted, however, that if a settlement is reached without a finding of patent infringement or invalidity, then a paragraph IV certification may continue to be appropriate.

We received no comments, and we are finalizing these proposed revisions to §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A) without change, except for a technical amendment to clarify that a settlement order or consent decree must be signed *and entered* by the court as required by section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act and the additional technical amendments described in sections V.P.2 and V.P.6.

V.E.2. Amended Certifications After Request by the NDA Holder To Remove a Patent or Patent Information From the List

We proposed to revise §§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B) to clarify the circumstances and timeframe in which a 505(b)(2) or ANDA applicant must submit an amended patent certification to its 505(b)(2) application or ANDA after an NDA holder has requested removal of a patent or patent information from the list (patent delisting). These proposed revisions also describe our practice regarding patent delisting as it relates to the eligibility of one or more first applicants for 180-day exclusivity.

We received one comment supporting our proposal that if an NDA holder has requested removal of a patent or patent information from the list and one or more first applicants are eligible for 180-day exclusivity, FDA will not remove the patent or patent information from the list until we have determined that no first applicant is eligible for 180-day exclusivity or the 180-day exclusivity is extinguished (see proposed §§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B)). We are finalizing proposed §§ 314.50(i)(6)(ii) and 314.94(a)(12)(viii)(B) with revisions to consistently refer to a request to remove a patent *or patent information* from the Orange Book and to clarify that the patent or patent information will remain listed until any 180-day exclusivity based on that patent has expired or has been extinguished. We also are making the technical amendments described in sections V.P.1, V.P.3, and V.P.6 and the revision to § 314.94(a)(12)(viii)(B) described in section V.E.3.

V.E.3. Amended Certifications Upon Patent Reissuance

We proposed to revise our regulations to describe a 505(b)(2) and ANDA applicant's patent certification obligations with respect to a reissued patent. Our approach reflected our consideration of the original patent and the reissued patent as a ''single bundle of patent rights,'' albeit patent rights that may have changed with reissuance, for purposes of administering the patent certification requirements of the FD&C Act and any 30-month stay of approval or 180-day exclusivity that relates to a paragraph IV certification to the original patent (see section V.B.1.e).

We proposed to require that a 505(b)(2) or ANDA applicant provide an appropriate patent certification or statement with respect to a reissued patent, unless the NDA holder did not timely file patent information with FDA on either the original patent or the reissued patent. We also proposed that the patent information listed for the reissued patent would be treated as though it had been submitted under 505(b)(1) or 505(c)(2) of the FD&C Act at the time of listing of the original patent for purposes of determining the availability of a 30-month stay if other criteria were met (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act).

For a first applicant eligible for 180-day exclusivity based on a paragraph IV certification to an original patent that is subsequently reissued, we proposed that if the applicant opined that the reissued patent also is invalid, unenforceable, or will not be infringed, the applicant must submit a paragraph IV certification to the reissued patent within 30 days of the date on which the reissued patent is listed in the Orange Book to lawfully maintain its paragraph IV certification for purposes of eligibility for 180-day exclusivity (see proposed § 314.94(a)(12)(viii)(B)). Otherwise, we proposed that we would consider the first applicant to have amended or withdrawn its paragraph IV certification to the original patent on which it qualified for 180-day exclusivity under section 505(j)(5)(D)(i)(III) of the FD&C Act. We indicated that if a first applicant who qualifies as such based on a paragraph IV certification to the original patent forfeits 180-day exclusivity, another applicant would not be eligible for 180-day exclusivity based on a paragraph IV certification to the reissued patent (see section 505(j)(5)(D)(iii)(II) of the FD&C Act).

In the following paragraphs, we discuss a comment on this proposal (see section V.B.1.e for a discussion of comments regarding submission of additional information on reissued patents). After considering this comment, we are not finalizing this proposal.

(Comment 38) One comment objects to FDA's proposal that a first applicant eligible for 180-day exclusivity based on a paragraph IV certification to a patent that has been reissued must submit a paragraph IV certification to the reissued patent within 30 days of listing to have lawfully maintained its paragraph IV certification for purposes of 180-day exclusivity. The comment asserts that failure to comply with this proposed requirement does not provide an adequate basis for FDA to extinguish a first applicant's eligibility for 180-day exclusivity. In the alternative, the comment requests that FDA expressly state that the requirement only will be applied prospectively. The comment also recommends that an amended patent certification only be required if the original certification becomes inaccurate.

(Response 38) As discussed in Response 17, FDA has determined that the ''single bundle of patent rights'' approach reflected in its proposed regulations on reissued patents is no longer appropriate based on the recent decision in *Mylan Pharms., Inc.* v. *FDA* (594 Fed. Appx. 791). Accordingly, the Agency is not finalizing the proposed revision to § 314.94(a)(12)(viii)(B) regarding reissued patents because we now consider reissued patents as separate and distinct from the original patent for purposes of administering the patent certification requirements of the FD&C Act and any 30-month stay of approval or 180-day exclusivity. This determination that the ''single bundle of patent rights'' approach is no longer appropriate means that FDA assesses whether a reissued patent is timely filed based solely on whether the NDA holder has submitted the required patent information within 30 days of reissuance (provided that the patent is reissued after the date of approval of the NDA) or otherwise meets the requirements for timely filing of patent information (see §§ 314.50(i)(4) and 314.94(a)(12)(vi)). Similarly, the date on which patent information on the reissued patent (and not the original patent) is submitted to FDA determines

whether a paragraph IV certification to the reissued patent could give rise to a 30-month stay if other criteria are met (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act). This also means that FDA evaluates eligibility for 180-day exclusivity based on whether the criteria are met for an original patent (irrespective of whether it subsequently is reissued) or for a reissued patent. It is unnecessary to address the comment requesting that FDA prospectively apply the proposed revision to § 314.94(a)(12)(viii)(B) because we are not finalizing this proposed change.

With respect to the comment regarding an ''amended'' patent certification, we note that an appropriate patent certification or statement is required for timely filed patent information submitted by an NDA holder for the listed drug relied upon or RLD, including timely filed patent information on a reissued patent (see §§ 314.50(i)(4) and 314.94(a)(12)(vi), and sections V.B.2.b and V.E.4; see also §§ 314.60(f) and 314.96(d) and section V.F).

V.E.4. Other Amended Certifications

We proposed to expressly require a 505(b)(2) or ANDA applicant to submit an appropriate patent certification or statement if, after submission of the 505(b)(2) application or ANDA, a new patent is issued by the USPTO that claims the listed drug or RLD or that claims an approved use for such drug, except as provided in §§ 314.50(i)(4) and 314.94(a)(12)(vi) (see proposed §§ 314.50(i)(6)(iii)(A)(*2*) and 314.94(a)(12)(viii)(C)(*1*)(*ii*)). We also explained our longstanding position that if an applicant that previously submitted a paragraph III certification, a paragraph IV certification, or a statement under section 505(b)(2)(B) or (j)(2)(A)(viii) of the FD&C Act fails to amend its patent certification to a paragraph II certification upon patent expiration, the Agency will consider the 505(b)(2) or ANDA applicant to have constructively changed its patent certification to a paragraph II certification. We proposed that a patent certification or statement by an ANDA applicant must not be submitted earlier than the first working day after the day the patent is published in the Orange Book (see proposed § 314.94(a)(12)(viii)(C)(*1*)(*ii*); see also proposed § 314.95(b)(2) and section V.D.1.a). Finally, we proposed to revise our regulations to clarify that an applicant is not required to submit a supplement solely to change a submitted patent certification after approval of the application (see proposed §§ 314.50(i)(6)(iii)(B) and 314.94(a)(12)(viii)(C)(*2*)).

In section V.D.1.a, we discuss comments on proposed § 314.94(a)(12)(viii)(C)(*1*)(*ii*) (see Responses 33 and 34). We received no other comments and are finalizing these provisions without change, except for the technical amendments described in section V.P.4.

V.F. Patent Certification Requirements for Amendments and Supplements to 505(b)(2) Applications and ANDAs (§§ 314.60, 314.70, 314.96, and 314.97)

V.F.1. Types of Amendments for Which Patent Certification Is Required

We proposed to add §§ 314.60(f) and 314.96(d) to clarify and augment the patent certification requirements for amendments described in §§ 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C). In these provisions, we proposed to require that an applicant must submit patent certifications described in §§ 314.50(i) or 314.94(a)(12) if approval is sought for any of the following types of amendments to a 505(b)(2) application or ANDA: (1) To add a new indication or other condition of use; (2) to add a new strength; (3) to make other than minor changes in the product formulation; or (4) to change the physical form or crystalline structure of the active ingredient of the drug product.

We explained that this proposed requirement would not apply to minor changes in product formulation that FDA would regard as resulting in essentially the same product (see proposed §§ 314.60(f)(3) and 314.96(d)(3)). We proposed that a new patent certification would not be required if the new formulation in the amendment is qualitatively (Q1) the same as the previous formulation (*i.e.,* contains all of the same inactive ingredients) and quantitatively (Q2) essentially the same (*i.e.,* each inactive ingredient differs by no more than plus or minus 5 percent from the previous formulation). If an applicant submits an amendment to a 505(b)(2) application or ANDA for any of the categories of changes described in these provisions and does not submit a new patent certification, we proposed that the applicant would be required to verify that the proposed change described in the amendment is not the type of change for which a new patent certification or statement is required (*e.g.,* the proposed formulation change meets the criteria for a ''minor'' formulation change).

In the following paragraphs, we discuss several comments on this proposal. After considering these comments, we are finalizing §§ 314.60(f) and 314.96(d) with revisions to clarify that the specified types of amendments are required to contain an appropriate patent certification (or recertification) or statement and to describe the required verification.

(Comment 39) Three comments recommend that an amended patent certification should not be required if the 505(b)(2) or ANDA applicant determines that the change described in its amendment does not materially affect the factual and legal basis for a previous paragraph IV certification or materially affect the product in a manner that could be protected by a listed patent. These comments express concern that requiring a patent certification for the types of amendments described in §§ 314.60(f) and 314.96(d) could give rise to a second 30-month stay of approval, contrary to the intent of the MMA. Two other comments opine that the proposal is under-inclusive, and recommend that FDA require a new patent certification in all circumstances in which an amendment may alter the proposed product's relationship to a listed patent and require that the applicant provide the basis for a claim of noninfringement. These comments recommend requiring a new patent certification (and corresponding opportunity for resolution of potential patent infringement claims before approval) if approval is sought for any of the following types of changes: Any change in product formulation; a change in the physical form, particle size, grade, purity, or crystalline structure of the active ingredient; or a change to a proposed drug-delivery device.

(Response 39) We acknowledge comments suggesting that the patent certification requirements for amendments to a 505(b)(2) application or ANDA may be considered either under-inclusive or over-inclusive. However, we believe that our approach strikes an appropriate balance by protecting the patent rights of NDA holders without unnecessarily delaying approval of 505(b)(2) applications and ANDAs. A 505(b)(2) or ANDA applicant is required to amend its patent certification if, at any time before approval, the applicant learns that the previously submitted patent certification is no longer accurate with respect to the pending application or supplement, as amended (see §§ 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C)). An applicant that submits a 505(b)(2) application or ANDA containing a paragraph IV certification to a listed patent must

reevaluate whether the patent certification continues to be accurate after a change to the proposed product submitted in an amendment to the 505(b)(2) application or ANDA. To address concerns that the factual and legal basis of the applicant's opinion that a patent will not be infringed may have changed, we are requiring an applicant to submit an appropriate patent certification (or recertification, for a previously submitted paragraph IV certification) or statement, for the following types of amendments to a 505(b)(2) application or ANDA: (1) To add a new indication or other condition of use; (2) to add a new strength; (3) to make other than minor changes in the product formulation; or (4) to change the physical form or crystalline structure of the active ingredient of the drug product (see §§ 314.60(f)(1) and 314.96(d)(1) and Response 42). These patent certification requirements are intended to facilitate ongoing compliance with section 505(b)(2)(A) and (j)(2)(A)(vii) of the FD&C Act. We do not agree that the need for an appropriate patent certification (or recertification) or statement for the types of amendments described in §§ 314.60(f) and 314.96(d) should be left entirely to the applicant's discretion because applicants may be uncertain when it is necessary. To implement the proposed verification by the 505(b)(2) or ANDA applicant described in the proposed rule (see 80 FR 6802 at 6823), we are adding §§ 314.60(f)(2) and 314.96(d)(2) to require that if the amendment to the 505(b)(2) application or ANDA does not contain a patent certification or statement, the applicant must verify that the proposed change described in the amendment is not one of the types of amendments described in §§ 314.60(f)(1)(i) through (iv) and 314.96(d)(1)(i) through (iv).

We also do not agree that it is necessary to expressly require an appropriate patent certification (or recertification) with the broader range of changes to a proposed product described in the comments. We previously have explained that ''[g]iven the range of changes that may be the subject of a [chemistry, manufacturing, and controls] amendment, such a requirement would impose a significant burden without clearly enhancing compliance with the statutory patent certification requirements. Through our proposal to require a new patent certification and, with respect to a paragraph IV certification, a new notice of paragraph IV certification to be sent at the same time that certain types of amendments are submitted to FDA, we are upholding the legislative balance of the Hatch-Waxman Amendments that facilitates the availability of generic drug products while protecting innovator intellectual property rights'' (see Letter from Janet Woodcock, M.D., Director, CDER, to John B. Dubeck and Frederick A. Stearns, dated February 6, 2015, regarding Docket No. FDA–2003–P–0519, available at *http://www.regulations.gov*).

We recognize that a 30-month stay of approval may result from initiation of a patent infringement action in response to a second notice of paragraph IV certification that is provided with an amendment to a 505(b)(2) application or ANDA. This scenario may occur if the patent at issue in the infringement action was listed before the date of submission of the original 505(b)(2) application or ANDA and, for example, the infringement action was warranted by the change proposed in the amendment (see, *e.g.,* Letter from Janet Woodcock, M.D., Director, CDER, to Gerald F. Masoudi, dated October 19, 2010, regarding Docket No. FDA–2010–P–0223, available at *http://www.regulations.gov* (concluding that a new 30-month stay of approval stems from a timely lawsuit based on the second notice of paragraph IV certification submitted in connection with an amendment to the ANDA for reformulated doxercalciferol injection); Letter from Janet Woodcock, M.D., Director, CDER, to Christina M. Markus, dated June 7, 2011, regarding Docket No. FDA–2011–P–0127, available at *http://www.regulations.gov* (confirming that a second 30-month stay of approval stems from a timely lawsuit based on the second notice of paragraph IV certification submitted in connection with an amendment to the ANDA for desflurane liquid)).

(Comment 40) One comment recommends that an amendment to a 505(b)(2) application or ANDA to add a new indication or other condition of use should only require submission of a patent certification to a patent that claims the new use and for which a patent certification previously was not made.

(Response 40) We agree that if an applicant amends its 505(b)(2) application or ANDA *only* to add a new indication or other condition of use, the applicant need only certify to listed patents that have been identified as claiming an approved use and relate to the change described in the amendment (provided that the 505(b)(2) application or ANDA contained an appropriate patent certification or statement to any other listed patent(s) prior to submission of the amendment). This approach preserves the NDA holder's intellectual property rights without requiring the 505(b)(2) or ANDA applicant to submit a duplicative certification to a listed patent(s) that has not been identified by the NDA holder as claiming a method of use and would not be implicated by the amendment (compare proposed § 314.70(i)(2)). This approach also is consistent with existing patent certification requirements under §§ 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C). If any other changes described in paragraphs (ii) through (iv) of §§ 314.60(f)(1) or 314.96(d)(1) are proposed in the amendment, the applicant would be required to address all timely filed listed patents for the listed drug relied upon or RLD with an appropriate patent certification (or recertification) or statement.

An ANDA applicant would be expected to submit an amendment to add a new indication or other condition of use if the applicant previously submitted a statement described in section 505(j)(2)(A)(viii) of the FD&C Act and now seeks approval for the use or if the RLD was approved for a new indication or other condition of use after the ANDA was submitted (see section 505(j)(2)(A)(v) of the FD&C Act and § 314.94(a)(8)(iv)). Most requests for approval of a different indication or condition of use by a 505(b)(2) applicant should not be made as an amendment to the 505(b)(2) application (see § 314.60(b)(6) and guidance for industry entitled ''Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees'' (December 2004) at 4 to 5, available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*). Accordingly, we expect that there would be limited circumstances in which this provision would apply to a 505(b)(2) application (*e.g.,* indication changed from prescription status to OTC use).

V.F.2. Types of Supplements for Which Patent Certification Is Required

We proposed to add §§ 314.70(i) and 314.97(c), and make conforming revisions to §§ 314.50(i)(6)(iii)(B) and 314.94(a)(12)(viii)(C)(*2*), to clarify the patent certification requirements for a 505(b)(2) or ANDA supplement. In these provisions, we proposed to require patent certifications described in § 314.50(i) or § 314.94(a)(12), if the applicant requests approval to add a new indication or other condition of use or to add a new strength in a 505(b)(2) or ANDA supplement (see proposed §§ 314.70(i) and 314.97(c)).

For a 505(b)(2) supplement that seeks approval for a new indication or other condition of use, the 505(b)(2) applicant currently is required to submit an appropriate patent certification or statement for each timely filed patent that claims the listed drug(s) relied upon or a method of using such drug(s) for which the applicant is seeking approval (see section 505(b)(2) of the FD&C Act). We proposed to reduce these patent certification requirements by providing that a 505(b)(2) supplement that only seeks approval to add a new indication or other condition of use is required to contain an appropriate patent certification or statement described in § 314.50(i) only for patents that are identified as claiming an approved use (see proposed § 314.70(i)(2)).

We did not propose to require a patent certification with a supplement to change the formulation or to change the physical form or crystalline structure of the active ingredient of a product approved in a 505(b)(2) application or ANDA. We explained that it would not be necessary for FDA to require patent certifications under these circumstances because the NDA holder for a listed drug and any patent owner can monitor postapproval changes in the formulation or active ingredient of a marketed drug product and address any patent-related concerns without the involvement of FDA.

In the following paragraphs, we discuss two comments on proposed §§ 314.70(i) and 314.97(c). We are continuing to consider these comments, and thus we are not finalizing proposed §§ 314.70(i) and 314.97(c) (or the references to these provisions in proposed §§ 314.50(i)(6)(iii)(B) and 314.94(a)(12)(viii)(C)(*2*)), respectively, at this time. Accordingly, FDA will maintain its current practice of regulating directly from the statute and general patent certification regulations in requiring an appropriate patent certification or statement with a 505(b)(2) or ANDA supplement.

(Comment 41) Two comments disagree with FDA's proposal to not expressly require a new patent certification with a 505(b)(2) or ANDA supplement in each of the circumstances in which a new patent certification (or recertification) is required for amendments to a 505(b)(2) application or ANDA. One comment maintains that the Agency's approach is inconsistent with the statute, which clearly describes patent certification requirements for 505(b)(2) and ANDA supplements. This comment also expresses concern that a 505(b)(2) or ANDA applicant could circumvent the patent certification requirements by seeking approval of a noninfringing product that the applicant does not intend to market followed by a supplement for a modified form of the active ingredient or a different formulation of the drug product that the applicant intends to market. Both comments contend that monitoring of postapproval changes by an NDA holder or patent owner is not a replacement for notice from the 505(b)(2) or ANDA applicant of a paragraph IV certification and the opportunity to litigate any potential infringement claims prior to approval of the change requested in the supplement.

(Response 41) We are continuing to evaluate these comments, including whether our regulations should expressly require a new patent certification with a broader range of changes submitted in supplemental applications than described in the proposed rule. Accordingly, we are declining to finalize proposed §§ 314.70(i) and 314.97(c) at this time. We will continue to implement the requirement for an appropriate patent certification or statement with a 505(b)(2) or ANDA supplement directly from the statute and our general regulations on patent certifications (see §§ 314.50(i)(6)(iii) and 314.94(a)(12)(viii)(C) (requiring a 505(b)(2) or ANDA applicant to amend its patent certification if, at any time before approval, the applicant learns that the previously submitted patent certification is no longer accurate with respect to the pending application or supplement)).

V.F.3. Requirements for Notice of Paragraph IV Certifications and Implications for 180-Day Exclusivity

We proposed that notice to the NDA holder and each patent owner would be required for all paragraph IV certifications, irrespective of whether the 505(b)(2) or ANDA applicant previously provided notice of paragraph IV certification to the same patent or to another patent claiming the listed drug relied upon or RLD (see section 505(b)(3)(B) and (j)(2)(B)(ii) of the FD&C Act and proposed §§ 314.52(d)(1) and 314.95(d)(1)). We proposed that a first applicant that submits an amendment to its pending ANDA or a supplement would be considered to have lawfully maintained a paragraph IV certification to the patent upon which eligibility for 180-day exclusivity was based if the amendment is accompanied by another paragraph IV certification to the patent and notice of paragraph IV certification is sent in accordance with proposed § 314.95(d).

In the following paragraphs, we discuss two comments on this topic. After considering these comments, we are revising proposed § 314.96(d) regarding amendments to an ANDA to clarify that a paragraph IV certification to a patent or patent claim for which an ANDA applicant previously submitted a paragraph IV certification is a ''recertification'' rather than an ''amendment'' of the paragraph IV certification. We are making conforming revisions to § 314.60(f). We are finalizing § 314.52(d)(1) with the changes described in Response 32, and we are finalizing § 314.95(d)(1) with the changes described in section V.D.1.b and the technical amendments described in section V.P.1.

(Comment 42) One comment expresses concern that a first applicant could inadvertently forfeit its eligibility for 180-day exclusivity if, pursuant to proposed § 314.96(d), the first applicant submits a new paragraph IV certification to the patent that qualified the applicant for 180-day exclusivity (see section 505(j)(5)(D)(i)(III) of the FD&C Act). The comment suggests that FDA require an ANDA applicant to provide a new notice of its paragraph IV certification to the NDA holder and each patent owner instead of submitting a new patent certification to the Agency. Another comment recommends that FDA not require an ANDA applicant to submit a new patent certification with an amendment to the ANDA if a patent infringement action already has been filed against the applicant with respect to the ANDA.

(Response 42) FDA interprets the statute to mean that a first applicant ''lawfully maintains'' a paragraph IV certification to the patent or patent claim upon which eligibility for 180-day exclusivity is based if any subsequent amendment to the ANDA that requires a patent certification contains a paragraph IV certification to the qualifying patent or patent claim and notice of the paragraph IV certification is sent in accordance with § 314.95(d). This interpretation is supported by our longstanding requirement that an ANDA applicant must amend a submitted certification if, at any time before approval of the ANDA, the applicant learns that the submitted certification is no longer accurate (see § 314.94(a)(12)(viii)(C)(*1*)(*i*)). A subsequent paragraph IV certification to the qualifying patent or patent claim is not an ''amendment'' of the previously submitted paragraph IV certification under section 505(j)(5)(D)(i)(III) of the FD&C Act because the type of certification remains the same; rather, it is a reaffirmation of the patent challenge

notwithstanding the amendment to the ANDA. Therefore, we are using the term ''recertification'' to describe this scenario (see § 314.96(d)(1); see also § 314.60(f)(1)).

We decline to adopt the comment's proposal to require a new notice of paragraph IV certification—but not a new patent certification—with an amendment to the ANDA. Notice of a paragraph IV certification is inextricably linked to the submission of a corresponding paragraph IV certification. The statute expressly requires that an applicant that submits a paragraph IV certification in an amendment to the ANDA provide the required notice at the time of submission of the amendment regardless of whether the applicant has already given notice with respect to another such certification contained in the application (see section 505(j)(2)(B)(ii)(II) of the FD&C Act). Notice of a new paragraph IV certification submitted with an amendment to the ANDA must be updated to correspond to the proposed product as changed by the amendment. However, we believe that the concern described in the comment is addressed by our explanation that a paragraph IV certification to a patent or patent claim for which an ANDA applicant previously submitted a paragraph IV certification is a ''recertification'' rather than an ''amendment'' of the paragraph IV certification and by the corresponding changes to § 314.96(d)(1).

We also do not agree with the suggestion that a new notice of paragraph IV certification should not be required if the NDA holder or owner of the relevant patent(s) already is litigating claims of patent infringement against the ANDA applicant. As previously discussed, the statute requires an ANDA applicant to provide notice with all paragraph IV certifications (see section 505(j)(2)(B)(ii)(II) of the FD&C Act). Moreover, if the factual and legal bases for the paragraph IV certification have changed, it would be particularly important to timely provide this information to the NDA holder and each patent owner to support the efficient use of judicial resources.

V.G. Amendments or Supplements to a 505(b)(2) Application for a Different Drug and Amendments or Supplements to an ANDA That Reference a Different Listed Drug (§§ 314.60, 314.70, 314.96, and 314.97)

V.G.1. Amendments and Supplements to an ANDA (§§ 314.96(c) and 314.97(b))

We proposed to establish a regulation that would implement section 505(j)(2)(D)(i) of the FD&C Act by providing that an ANDA applicant may not amend or supplement an ANDA to seek approval of a drug referring to a listed drug that is different from the RLD identified in the ANDA (see proposed §§ 314.96(c) and 314.97(b)). For example, we proposed that if at any time before approval of the ANDA, an NDA is approved for a drug product that is pharmaceutically equivalent to the proposed product in the pending ANDA and that NDA is designated as an RLD, the applicant would not be permitted to amend its pending ANDA to reference the new RLD (see proposed § 314.96(c)). We proposed that this restriction also would apply if one or more changes proposed in an amendment or a supplement to an ANDA would result in the proposed product being a pharmaceutical equivalent to a different listed drug than the RLD identified in the ANDA. In these scenarios, we proposed that the ANDA applicant would be required to submit a new ANDA to identify the pharmaceutically equivalent product as the new RLD (see proposed §§ 314.96(c) and 314.97(b) and section 505(j)(2)(D)(i) of the FD&C Act).

In the proposed rule, we confirmed that different strengths of an approved drug product continue to be regarded as different listed drugs. However, to implement section 505(j)(2)(D)(ii) of the FD&C Act, we proposed to codify our practice that permits an applicant to amend or supplement an ANDA to seek approval of a different strength of the drug (see proposed §§ 314.96(c) and 314.97(b)).

We received no comments on proposed § 314.97(b) regarding supplements. In the following paragraphs, we discuss three comments on proposed § 314.96(c) regarding amendments. After considering these comments, we are finalizing proposed §§ 314.96(c) and 314.97(b) without change.

(Comment 43) One comment requests that FDA modify the proposed regulation to require that if, at any time before submission (rather than any time before approval) of the ANDA, an NDA is approved for a drug product that is pharmaceutically equivalent to the proposed product and that NDA is designated as an RLD, the ANDA applicant would be required to submit an ANDA that identifies the pharmaceutically equivalent product as the RLD. The comment suggests that this proposed revision (and a similar proposal discussed in comment 49) would harmonize FDA's proposed requirements for ANDAs and 505(b)(2) applications by imposing limitations up until the time of ANDA submission rather than approval. Another comment expresses concern that requiring an ANDA applicant to submit a new ANDA that identifies the pharmaceutically equivalent product as the RLD may unnecessarily require additional data and delay ANDA approval, although the comment acknowledges that this may be appropriate and efficient in some circumstances.

(Response 43) We decline to adopt the suggested modification to proposed § 314.96(c). Under existing practice, FDA will refuse to receive an ANDA that does not cite an appropriate RLD or rely on an approved suitability petition as its basis for ANDA submission (see § 314.94(a)(3)). In addition, there are circumstances in which an ANDA that has been received, but not approved, may be required to submit a new ANDA that identifies a pharmaceutically equivalent product as the RLD. This may occur, for example: (1) If a pharmaceutically equivalent product is approved after an ANDA is submitted pursuant to an approved suitability petition (petitioned ANDA) or (2) if changes are proposed in an amendment or a supplement to the ANDA such that the proposed product is pharmaceutically equivalent to a different listed drug than the RLD identified in the original ANDA (modified ANDA). Before enactment of the MMA, FDA required an applicant to amend its ANDA in these scenarios to cite the pharmaceutically equivalent product as its RLD. However, the MMA prohibits an ANDA applicant from amending its ANDA to change the RLD (see section 505(j)(2)(D)(i) of the FD&C Act). Accordingly, for the applicant to obtain approval of the proposed product under section 505(j) of the FD&C Act in these scenarios, we require the applicant to submit a new ANDA that identifies the pharmaceutically equivalent product as its RLD and complies with applicable statutory and regulatory requirements.

We require an ANDA applicant to identify as its RLD a pharmaceutically equivalent product approved any time before approval, rather than submission, of the ANDA, because a generic drug product must demonstrate, among other things, that it is bioequivalent to the

RLD to obtain approval (see section 505(j)(2)(A)(iv) of the FD&C Act and § 314.127(a)(6)(i)). We disagree that an ANDA applicant should only be required to identify a pharmaceutically equivalent product as its RLD until submission of the ANDA, because this approach would not ensure that an ANDA applicant cites an appropriate RLD in the context of a petitioned ANDA or modified ANDA unless the RLD was approved before submission of the ANDA. Such an approach would foster a potentially confusing proliferation of pharmaceutically equivalent drug products that have not demonstrated therapeutic equivalence to the RLD. The additional data and time that may be needed for an ANDA applicant to identify a pharmaceutically equivalent drug product as the RLD is warranted by the need for a clear determination of therapeutic equivalence. The modification requested in the comment would ''diminish the utility and accuracy of FDA's therapeutic equivalence determinations and potentially allow ANDA applicants to circumvent otherwise applicable patent and exclusivity rights accorded the NDA holder for the pharmaceutically equivalent RLD'' (see Letter from Janet Woodcock, M.D., Director, CDER, to Mark S. Aikman, Pharm.D., Osmotica Pharmaceutical Corp., dated November 25, 2008, regarding Docket No. FDA–2008–P–0329, at 11–12, available at *http://www.regulations.gov*) (Venlafaxine ER CP Response).

Unlike an ANDA that relies on a single RLD, a 505(b)(2) application may rely for approval on one or more listed drugs and is not required to demonstrate bioequivalence or pharmaceutical equivalence to a listed drug on which it relies for approval. Although the Agency requires a 505(b)(2) applicant to rely upon a drug product approved in an NDA that is pharmaceutically equivalent to the proposed product, the basis and timeframe for this requirement for 505(b)(2) applications differs from that of ANDAs.

(Comment 44) One comment recommends that FDA permit an ANDA applicant to amend its ANDA if FDA changes the RLD or the ANDA applicant petitions to change the RLD.

(Response 44) The comment is unclear because the Agency's designation of an additional RLD or selection of a new reference standard generally would not require an ANDA applicant to change its RLD. The RLD is the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA (see § 314.3(b)). An ANDA applicant is prohibited from amending or supplementing its ANDA to change the RLD after the ANDA has been submitted (see §§ 314.96(c) and 314.97(b) and section 505(j)(2)(D)(i) of the FD&C Act).

We note that if there are two or more approved NDAs for pharmaceutically equivalent products, a person may submit a citizen petition requesting that FDA designate an additional RLD, provided that there is adequate justification (see ''Abbreviated New Drug Application Regulations; Final Rule,'' 57 FR 17950 at 17958, April 28, 1992, and section 1.4 of the preface to the Orange Book (36th Edition, 2016, at ix) (recognizing that a listed drug that is not designated as the RLD may be shielded from generic competition)). An ANDA would not be ineligible for approval because it relied on one of two or more RLDs that were approved under section 505(c) of the FD&C Act based on full reports of investigations of safety and effectiveness, provided that other statutory and regulatory requirements are met. Thus, an applicant is not required to change its RLD upon FDA designation of the additional RLD.

Generally, the RLD also will be the reference standard, which is the drug product selected by FDA that an ANDA applicant must use in conducting an in vivo bioequivalence study required for ANDA approval (see §§ 314.3(b) and 314.94(a)(3)). FDA usually selects as the reference standard the highest strength available for drug products with multiple approved strengths. However, a person may petition the Agency to request that FDA designate a new reference standard for conducting bioequivalence testing if, for example, the person believes that another drug product would be a scientifically appropriate reference standard, or if the drug product selected as the reference standard has been discontinued and FDA has not selected a new reference standard. FDA also may select a reference standard in the absence of a citizen petition (see Letter from Janet Woodcock, M.D., Director, CDER, to Paul A. Braier, Ph.D., J.D., dated September 5, 2014, regarding Docket No. FDA–2014–P–0417, at 11, available at *http://www.regulations.gov*). For example, if the RLD has been withdrawn from marketing for reasons other than safety or effectiveness, FDA may select a different drug product (*e.g.,* a different strength of a drug product that is the RLD) or a therapeutically equivalent drug product (*e.g.,* an approved ANDA that cited the RLD as its basis of submission) as the reference standard. Even if FDA selects a reference standard that is a drug product other than the RLD for use in conducting an in vivo bioequivalence study, the proposed drug product will be evaluated against the RLD to determine whether it meets the statutory requirements for approval under section 505(j) of the FD&C Act. An applicant also may request, with appropriate scientific justification, that FDA waive the requirement to use the drug selected by FDA as the reference standard in an in vivo bioequivalence study required for approval (see § 314.99(b)).

FDA's selection of a different reference standard or waiver of the requirement to use the reference standard generally would not result in a change to the RLD. An ANDA would not be ineligible for approval because it relied upon an RLD that was not selected as a reference standard.

We acknowledge that FDA's practice of identifying the reference standard in the Orange Book by the word ''yes'' in the ''RLD'' column has resulted in confusion, and we are revising the column heading in the Orange Book from ''RLD'' to ''RS'' for clarity.

V.G.2. Amendments and Supplements to a 505(b)(2) Application (§§ 314.60(e) and 314.70(h))

We proposed to establish a regulation that would implement section 505(b)(4)(A) of the FD&C Act by providing that an applicant may not amend or supplement a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the original submission of the 505(b)(2) application (see proposed §§ 314.60(e) and 314.70(h)). We proposed that a drug will be considered a ''different drug'' for purposes of section 505(b)(4)(A) of the FD&C Act if it has been modified to have a different active ingredient, different route of administration, different dosage form, or different excipients that require either a separate clinical study to establish safety or effectiveness or, for topical products, that require a separate in vivo demonstration of bioequivalence (see proposed §§ 314.60(e) and 314.70(h)). These proposed modifications would result in a different drug for which approval must be requested in a new 505(b)(2) application.

In the proposed rule, we explained that the statutory restriction on amending a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the original submission of the 505(b)(2) application applies to any proposed amendment, even if the amendment is submitted before the Agency's decision regarding whether the 505(b)(2) application can be filed in accordance with § 314.101(a). However, notwithstanding these

restrictions on amendments to a 505(b)(2) application, we proposed that an applicant is permitted to amend or supplement a 505(b)(2) application to identify a new or additional listed drug upon which the application relies for approval as long as the applicant is not seeking approval for a different drug from the drug in the original submission of the 505(b)(2) application. In addition, we proposed that an applicant is permitted to amend or supplement a 505(b)(2) application to seek approval for a different strength of the drug product (see section 505(b)(4)(B) of the FD&C Act and proposed §§ 314.60(e) and 314.70(h)).

We received no comments on proposed § 314.70(h) regarding supplements. In the following paragraphs, we discuss a comment on proposed § 314.60(e) regarding amendments. After considering this comment, we are finalizing proposed §§ 314.60(e) and 314.70(h) without change.

(Comment 45) One comment recommends that FDA return to its initial interpretation of section 505(b)(4)(A) of the FD&C Act and revise § 314.60(e) to prohibit a 505(b)(2) applicant from amending its application to rely upon a new or different listed drug for approval. The comment observes that if a new or different listed drug is identified in an amendment to the 505(b)(2) application, and the 505(b)(2) applicant submits a paragraph IV certification for a patent that is timely filed after submission of the 505(b)(2) application, a 30-month stay would not be available should the NDA holder or patent owner initiate patent infringement litigation within the statutory timeframe.

(Response 45) We decline to revise § 314.60(e) as requested because the comment does not provide any basis for a different interpretation of section 505(b)(4)(A) of the FD&C Act that FDA did not expressly consider in the proposed rule. The preamble to the proposed rule contains an extensive discussion of the Agency's initial interpretation of section 505(b)(4)(A) of the FD&C Act and explains why FDA proposed narrowing that interpretation of section 505(b)(4)(A) of the FD&C Act as reflected in §§ 314.60(e) and 314.70(h) (see 80 FR 6802 at 6850 through 6852). The comment has not persuaded us to return to that initial interpretation.

V.H. Procedure for Submission of a 505(b)(2) Application Requiring Investigations for Approval of a New Indication for, or Other Change From, a Listed Drug (§ 314.54)

We proposed to require that the listed drug(s) identified as relied upon by a 505(b)(2) applicant must include any approved drug product that: (1) Is pharmaceutically equivalent to the drug product for which the 505(b)(2) application is submitted and (2) was approved before the 505(b)(2) application was submitted (see proposed §§ 314.50(i)(1)(i)(C), 314.54(a)(1), and 314.125(b)(19)).

In the following paragraphs, we discuss a comment on these proposed provisions. After considering this comment, we are finalizing proposed § 314.54(a)(1) with revisions to clarify that a 505(b)(2) applicant must identify a pharmaceutically equivalent drug product approved in an NDA as a listed drug (or an additional listed drug) relied upon if the pharmaceutically equivalent drug product was approved before the date of submission of the original 505(b)(2) application, and to codify the basis for this requirement. If there is more than one drug product that is pharmaceutically equivalent to the drug product for which the original 505(b)(2) application is submitted and was approved in one or more NDAs before the original 505(b)(2) application was submitted, the 505(b)(2) applicant is only required to identify one such pharmaceutically equivalent drug product as a listed drug relied upon. We are finalizing proposed §§ 314.50(i)(1)(i)(C) and 314.125(b)(19) with conforming revisions.

(Comment 46) One comment suggests that FDA require a 505(b)(2) applicant to identify any approved pharmaceutically equivalent drug product as a listed drug relied upon to support approval of the proposed product irrespective of whether the pharmaceutically equivalent product was approved before or during the review of the 505(b)(2) application. The comment proposes that if a pharmaceutically equivalent product is approved after a 505(b)(2) application is submitted, the 505(b)(2) applicant—like an ANDA applicant—should be required to file a new 505(b)(2) application to ensure that the NDA holder for the pharmaceutically equivalent drug product has a reasonable opportunity for a 30-month stay and that any non-patent exclusivity is meaningful.

(Response 46) We decline to modify the regulations as suggested. If a pharmaceutically equivalent drug product is approved before an original 505(b)(2) application is submitted, we consider the 505(b)(2) applicant to implicitly rely upon FDA's finding of safety and effectiveness for one such pharmaceutically equivalent drug product for approval even if the proposed drug product was developed independently of that pharmaceutically equivalent drug product. Accordingly, we require the 505(b)(2) applicant to identify one pharmaceutically equivalent drug product approved in an NDA as a listed drug (or an additional listed drug) relied upon and comply with applicable regulatory requirements. A 505(b)(2) applicant that identifies a listed drug solely to comply with § 314.54(a)(1)(vi) must provide an appropriate patent certification or statement for any patents that are listed in the Orange Book for the pharmaceutically equivalent drug product, but the 505(b)(2) applicant is not required to submit bridging data to justify the scientific appropriateness of reliance on the pharmaceutically equivalent drug product if it is scientifically unnecessary to support approval. Given that there cannot be any implicit reliance on FDA's finding of safety and effectiveness for a drug product that has not yet been approved, this rationale would not support a requirement for a 505(b)(2) applicant to identify a pharmaceutically equivalent drug product approved in an NDA after the 505(b)(2) application is submitted. We are revising § 314.54(a)(1)(vi) to clarify the basis for this requirement, which establishes a bright line requirement for administering the patent certification requirements of the FD&C Act and is unrelated to our approach to implementing section 505(b)(4)(A) of the FD&C Act. We are further revising the regulations to clarify that the requirement to identify one pharmaceutically equivalent drug product approved in an NDA as a listed drug (or an additional listed drug) relied upon applies before the date of submission of an original 505(b)(2) application and not a resubmission or a supplement (see, *e.g.,* § 314.54(a)(1); see also § 314.3(b) (definitions of ''original NDA'' and ''resubmission'')). We also are making conforming revisions to § 314.54(a)(1)(iii) and (vi) to clarify that a 505(b)(2) application may rely on FDA's finding of safety and/or effectiveness for one or more listed drugs.

We recognize that a 505(b)(2) applicant that does not amend its pending 505(b)(2) application to rely upon a pharmaceutically equivalent listed drug would have no occasion to submit a patent certification or

statement with respect to any patents listed for the listed drug (and could be subject to patent infringement litigation after approval). This illustrates one of many circumstances in which the timing of submission of an application has certain statutory or regulatory implications (see, *e.g.,* untimely filing of patent information). However, to the extent that the 505(b)(2) application is seeking approval for the exclusivity-protected conditions of approval for the listed drug, approval of the 505(b)(2) application would be delayed by any applicable 3-year exclusivity for the listed drug irrespective of reliance (see *Veloxis Pharms.* v. *FDA,* 109 F. Supp. 3d 104, 120 (D.D.C. 2015)).

(Comment 47) One comment suggests that FDA require a 505(b)(2) applicant to identify any approved drug product that is a pharmaceutical alternative to the proposed product as a listed drug(s) relied upon to support approval of the proposed product.

(Response 47) We decline to modify the regulations as suggested. Pharmaceutical alternatives are drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form or as the same salt or ester (see § 314.3(b)). Accordingly, there may be numerous pharmaceutical alternatives to a particular drug product. Given that a proposed drug product intended for submission in a 505(b)(2) application may differ in various respects from the listed drug(s) on which it relies for approval, there is insufficient justification to require a 505(b)(2) applicant to identify any pharmaceutical alternative (in addition to one pharmaceutical equivalent) as a listed drug upon which the 505(b)(2) application relies in the absence of explicit reliance (see Letter from Janet Woodcock, M.D., Director, CDER, to David B. Clissold, J.D., dated September 18, 2013, regarding Docket Nos. FDA–2011–P–0869 and FDA–2013–P–0995, at 8, available at *http://www.regulations.gov*) (''except where a pharmaceutical equivalent already has been approved, the 505(b)(2) applicant should determine which listed drug(s) is most appropriate for its development program'').

We consider the 505(b)(2) applicant to implicitly rely for approval upon FDA's finding of safety and effectiveness for one such pharmaceutically equivalent listed drug approved in an NDA because the proposed product shares key characteristics (active ingredient, dosage form, route of administration, and strength) in common with the listed drug despite being ineligible for approval under section 505(j) of the FD&C Act (see § 314.101(d)(9)). As we explained in the proposed rule, the requirement to identify a pharmaceutically equivalent product approved in an NDA as a listed drug upon which the 505(b)(2) application relies ''is intended to help ensure that the 505(b)(2) pathway is not used to circumvent the statutory obligation that would have applied if the proposed product was submitted as an ANDA—namely, submission of a patent certification for a listed patent that corresponds to the protected aspects of the pharmaceutically equivalent listed drug'' (80 FR 6802 at 6856).

(Comment 48) One comment recommends that FDA clarify that the requirement for a 505(b)(2) applicant to identify an approved pharmaceutically equivalent product as a listed drug relied upon does not extend to a complex drug product for which there may be uncertainty about whether the drug contains the ''identical'' or ''same'' active drug ingredient.

(Response 48) We acknowledge that a 505(b)(2) applicant may be uncertain whether to identify a listed drug solely to comply with §§ 314.50(i)(1)(i)(C), 314.54(a)(1), and 314.125(b)(19) due to the applicant's uncertainty about whether the drug contains the ''identical'' active drug ingredient or meets other criteria for a pharmaceutical equivalent. FDA intends to consider on a case-by-case basis any assertions by a prospective 505(b)(2) applicant that there is uncertainty about whether a previously approved drug product contains the ''identical'' active drug ingredient as the proposed product.

V.I. Petition To Request a Change From a Listed Drug (§ 314.93)

We proposed to codify FDA's policy that the listed drug identified in an approved suitability petition can no longer be the basis for submission for an unapproved ANDA after a drug product is approved in an NDA for the change described in the petition, irrespective of whether FDA has withdrawn approval of the suitability petition (see proposed § 314.93(f)). We proposed that an applicant may not amend its ANDA to change the basis for submission to the new RLD (see section 505(j)(2)(D)(i) of the FD&C Act and proposed § 314.96(c)), and would be required to submit a new ANDA that relies on the pharmaceutically equivalent RLD if the applicant seeks approval for the drug product. Accordingly, we proposed to add § 314.127(a)(14) to state that FDA will refuse to approve a petitioned ANDA if an NDA subsequently has been approved for the change described in the suitability petition. We also proposed to add § 314.93(e)(1)(vi) to codify our longstanding policy that FDA will not approve a suitability petition if a drug product is approved in an NDA for the change requested in the petition.

One comment agreed with these proposed revisions to our regulations on suitability petitions. In the following paragraph, we discuss two other comments on the proposal. After considering these comments, we are finalizing proposed § 314.93(e) and (f) with the technical amendment described in section V.P.1. We are also finalizing proposed § 314.127(a)(14) with technical amendments to describe an approved ''suitability petition'' as an approved petition under 21 CFR 10.30 and § 314.93, and we are making conforming revisions to § 314.94(a)(3)(i) and (iii).

(Comment 49) Two comments recommend that FDA revise the proposed regulation to require that if, at any time before submission (rather than any time before approval) of an ANDA based on a suitability petition, an NDA is approved for the change described in the suitability petition, the ANDA applicant would be required to submit an ANDA that identifies the drug product approved in the NDA as the RLD. One comment suggests that this proposed revision would harmonize FDA's proposed requirements for ANDAs and 505(b)(2) applications with respect to the timeframe in which an applicant must rely upon a pharmaceutically equivalent product. The other comment observes that there still may be multiple versions of a drug product because one or more ANDAs may have been approved pursuant to the suitability petition before an NDA is approved for the change described in the petition.

(Response 49) We decline to adopt the suggested modification to §§ 314.93 and 314.127(a)(14). FDA's longstanding practice, as described in the letter granting a suitability petition, is that once a drug product is approved in an NDA for the change described in the petition, that drug product will be the RLD and thereafter the approved suitability petition may not be used as the basis for submission of an ANDA. Accordingly, if an NDA is approved for the change described in the suitability petition before submission of an ANDA pursuant to an approved suitability petition, FDA would refuse to receive the ANDA. If an NDA is approved for the change described in the suitability petition after submission or receipt of an ANDA and is designated as the RLD, the applicant would be required to submit a new ANDA that cites the RLD as its basis for submission, and complies with

applicable statutory and regulatory requirements for approval. As we explained in the proposed rule, our requirement that an applicant with a pending ANDA subject to an approved suitability petition change the RLD upon FDA approval of an NDA for the same drug product described in the approved suitability petition ''reflects the Agency's judgment that considerations regarding an ANDA's limited reliance on an approved suitability petition are outweighed by the need for a clear determination of therapeutic equivalence for a generic drug product and protection of intellectual property rights accorded an NDA holder'' (80 FR 6802 at 6853, quoting Venlafaxine ER CP Response at 9).

V.J. Filing an NDA and Receiving an ANDA (§ 314.101)

V.J.1. Notification of Filing of a 505(b)(2) Application or Receipt of an ANDA

We proposed to clarify that FDA will notify the applicant that the 505(b)(2) application is regarded as filed or the ANDA is regarded as received by means of a paragraph IV acknowledgment letter if the 505(b)(2) application or ANDA contains a paragraph IV certification (see proposed § 314.101(a)(2) and (b)(2); see also sections V.A.1 and V.D.1.a). We received no comments regarding these proposed revisions, and we are finalizing proposed § 314.101(a)(2) without change, and § 314.101(b)(2) with the clarifying revisions discussed in section V.J.2.

V.J.2. Refuse-to-Receive Decisions for ANDAs

We proposed to revise § 314.101(b)(1) and (2) regarding ANDAs to incorporate the statutory definition of a ''substantially complete application,'' which was added by the MMA for purposes of section 505(j)(5) of the FD&C Act (see section 505(j)(5)(B)(iv)(II)(cc) of the FD&C Act and section V.A.5). We proposed that receipt of an ANDA means that FDA has made a threshold determination that the ANDA is substantially complete (see proposed § 314.101(b)(1)). We proposed to revise § 314.101(b)(2) to clarify that if an ANDA is determined to have been substantially complete as of the date on which it was submitted, the date of submission is considered to be the date of receipt. We also proposed to amend § 314.101(b)(3) to update the regulations to reflect our current practice for advising an ANDA applicant that FDA has refused to receive the ANDA under § 314.101(d) or (e).

In the following paragraphs, we discuss three comments on these proposed revisions. After considering these comments, we are making clarifying revisions to proposed § 314.101(b)(2). We are finalizing proposed § 314.101(b)(3) and (d)(3) with revisions to more precisely describe the factors that FDA considers in determining whether an ANDA is incomplete on its face, and the actions that an ANDA applicant may take following a refuse-to-receive decision.

(Comment 50) Two comments recommend that FDA clarify its regulations regarding refuse-to-receive standards in light of the policy described in its guidance for industry entitled ''ANDA Submissions—Refuse-to-Receive Standards'' (May 2015), available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*. One of these comments maintains that the current regulation permits applicants to amend an ANDA to address deficiencies irrespective of the number of deficiencies or whether the deficiencies are major or minor. This comment asserts that FDA would need to reissue the proposed rule to incorporate the standards described in the guidance. Another comment suggests that FDA limit the time for a completeness evaluation to 90 days, and permit applicants to amend an ANDA to address minor deficiencies that can be corrected within 30 days.

(Response 50) FDA agrees with the recommendations to clarify its regulations regarding refuse-to-receive standards for ANDAs. To address these comments, FDA is revising § 314.101(d)(3) to codify its current practice of considering the nature (*e.g.,* major or minor) of the deficiencies, including the number of deficiencies in the ANDA, in determining whether an ANDA is incomplete on its face. This approach reflects the goal of FDA's filing regulations, which encourage applicants to submit complete ANDAs and conserve FDA resources by permitting FDA reviewers to devote their time to examining reviewable applications (57 FR 17950 at 17965).

To clarify the actions that an ANDA applicant may take following a refuse-to-receive decision, FDA is revising § 314.101(b)(3)(ii) to state that if the ANDA is not received, the applicant may correct the deficiencies and resubmit the ANDA. This amendment reflects the statutory procedures for ANDAs that FDA considers not to have been received (see section 744B(a)(3)(E) of the FD&C Act (21 U.S.C. 379j–42(a)(3)(E) (describing the user fee requirements for resubmission of an ANDA that FDA considers not to have been received or that has been withdrawn)). FDA also is revising § 314.101(b)(3)(iii) to clarify that if the ANDA is not received, the applicant may take no action, in which case FDA may consider the ANDA withdrawn after 1 year. An ANDA applicant's failure to take action after a refuse-to-receive decision on an ANDA may be considered a request by the applicant to withdraw the ANDA, unless the applicant requests an extension of time in which to resubmit the ANDA. This revision eliminates the circularity of the former text, which provided that if the ANDA is refused for receipt and the applicant takes no action, FDA will refuse to receive the ANDA.

Finally, FDA is revising § 314.101(b)(2) to clarify that if FDA determines, upon evaluation, that an ANDA was substantially complete as of the date it was submitted to FDA, FDA will consider the ANDA to have been received as of the date of submission. We are making a conforming revision to § 314.101(b)(1) to change ''reviewed'' to ''evaluated'' to clarify that FDA's evaluation does not involve a substantive review of the data in the ANDA. We disagree with the comment's suggestion that reissuance of the proposed rule is necessary for these clarifying revisions to § 314.101 because the revisions are not changing the standard for refuse-to-receive decisions, but are merely clarifying how FDA has been implementing the standard.

(Comment 51) One comment recommends that FDA provide a mechanism for ANDA applicants to challenge a refuse-to-receive decision analogous to the procedures described in § 314.101(a)(3) for NDA applicants.

(Response 51) FDA declines to adopt the suggestion because a revision to the regulations is not necessary to provide a mechanism for ANDA applicants to dispute a refuse-to-receive decision. ANDA applicants can avail themselves of existing mechanisms to discuss or dispute a refuse-to-receive action, including the dispute resolution procedure in § 314.103.

V.J.3. Administrative Consequence for Late Notice

We proposed to establish an administrative consequence for an ANDA applicant that fails to timely provide notice of a paragraph IV certification (see section 505(j)(2)(B)(ii) of the FD&C Act). We proposed that if FDA determines that an ANDA applicant did not send notice of a paragraph IV certification within the timeframe described in § 314.95(b) or (d), as applicable, FDA will deem the

date that the ANDA was submitted to be delayed by the number of days by which the timeframe for sending notice of a paragraph IV certification was exceeded (see proposed § 314.101(b)(4)). This proposal created the potential for an ANDA applicant to lose its first-applicant status and thus its eligibility for 180-day exclusivity as a result of providing late notice, if another applicant were to submit a substantially complete ANDA containing a paragraph IV certification on the same first day and were to provide timely notice (see section 505(j)(5)(B)(iv) of the FD&C Act). We noted that this proposed administrative consequence would not reduce the 30-month timeframe set forth in section 505(j)(5)(D)(i)(I)(aa)(BB) and (j)(5)(D)(i)(IV) of the FD&C Act in the forfeiture calculus for a first applicant; rather, the 30-month period would begin on the revised date of submission.

Two comments support FDA's proposed administrative consequence for failure to send notice of paragraph IV certification within the required timeframe. In the following paragraphs, we discuss two other comments on this proposal. After considering these comments, we are not finalizing proposed § 314.101(b)(4).

(Comment 52) One comment asserts that the statutory consequence for an ANDA applicant's delay in sending notice of paragraph IV certification is a commensurate delay in the start of any resultant 30-month stay of approval. The comment contends that the Agency has no legal authority to impose an additional sanction, and that the proposal should be withdrawn. Another comment recommends that the administrative consequence for a first applicant be modified to reduce the 180-day exclusivity period by the number of days that notice was late and avoid the potential loss of eligibility for 180-day exclusivity.

(Response 52) Although we believe that the Agency has the authority to establish an administrative consequence for an ANDA applicant's failure to comply with the statutory timeframe for sending notice of paragraph IV certification, we currently do not consider the administrative consequence to be necessary in light of other incentives for ANDA applicants to timely provide notice of a paragraph IV certification. Based on the Agency's implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA) in Title III of FDASIA and the GDUFA goals for expeditious review of ANDAs, FDA is approving ANDAs more quickly and ANDA applicants are unlikely to delay sending notice of paragraph IV certification because such a delay might result in a delay in ANDA approval. A 505(b)(2) or ANDA applicant that provides late notice of a paragraph IV certification risks that the NDA holder or patent owner will file an action for patent infringement within the 45-day period after notice, and that any resultant 30-month stay will delay approval by a period of time commensurate with the 505(b)(2) or ANDA applicant's delay in sending notice. We believe this potential delay in approval will incentivize 505(b)(2) and ANDA applicants to comply with the statutory timeframe for sending notice, and provide adequate opportunity for an NDA holder or patent owner to assert certain intellectual property rights prior to approval. Accordingly, we are declining to finalize the proposed administrative consequence as unnecessary at this time.

V.J.4. Other Proposed Revisions

We proposed several clarifying revisions to § 314.101. First, we proposed to delete the reference to section 507 of the FD&C Act in § 314.101(d)(3) to reflect statutory changes made by the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115). Second, we proposed to replace the term ''application'' in § 314.101(d)(6) and (7) with ''NDA or ANDA'' to clarify that these provisions apply to ANDAs as well as NDAs. Third, we proposed to replace the current text of § 314.101(e)(2) with a statement that FDA will refuse to file a 505(b)(2) application or will consider an ANDA not to have been received if submission of a 505(b)(2) application or an ANDA is not permitted under § 314.108(b)(2).

We received no comments regarding these proposed revisions, and we are finalizing these revisions to § 314.101(d)(3), (6), and (7) without change. We are making conforming revisions to § 314.101(d)(5) and the paragraph heading for § 314.101(d). As discussed in section V.A.7, we are revising § 314.101(e)(2) to remove the cross-reference to § 314.108(b)(2) because that section does not address all of the potential exclusivities that would preclude a 505(b)(2) application or ANDA from being filed or received. We are also revising § 314.101(e)(2) to expressly state that FDA will refuse to file an NDA or will consider an ANDA not to have been received if submission of a 505(b)(2) application or an ANDA is not permitted under section 505(c)(3)(E)(ii), 505(j)(5)(F)(ii), 505A(b)(1)(A)(i)(I), 505A(c)(1)(A)(i)(I), or 505E(a) of the FD&C Act.

V.K. Approval of an NDA and ANDA (§ 314.105)

We proposed to revise § 314.105(a) and (d) regarding approval of an NDA and an ANDA to remove the references to a ''delayed effective date'' and clarify that an application is approved on the date of issuance of an approval letter. We explained in the proposed rule that the Agency does not issue approval letters with delayed effective dates. Rather, the Agency will issue a tentative approval letter when an NDA or ANDA that is otherwise eligible for approval cannot be approved because of unexpired patents, certain circumstances related to patent litigation, or various types of exclusivity.

In addition, we proposed to revise § 314.105(a) and (d) to expressly state that FDA's tentative approval of a drug product is based on information available to FDA at the time of the tentative approval letter (*i.e.,* information in the 505(b)(2) application or ANDA and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA's attention.

We received no comments regarding these proposed revisions. We are finalizing § 314.105 without change, except for the technical amendments described in section V.A.3 and V.A.7 to reflect the enactment of GAIN and IRTNMTA, respectively.

V.L. Refusal To Approve an NDA or ANDA (§§ 314.125 and 314.127 and Related Provisions in §§ 314.90 and 314.99)

We proposed to revise §§ 314.90 and 314.99 to clarify that if FDA grants an applicant's request for waiver of a requirement under §§ 314.50 through 314.81 or §§ 314.92 through 314.99, respectively, the applicant's failure to comply with the requirement that is the subject of the waiver request will not constitute a basis for refusal to approve the NDA under § 314.125 or the ANDA under § 314.127. We also proposed corresponding revisions to §§ 314.125(b) and 314.127(a), which address permissive refusal to approve an NDA and mandatory refusal to approve an ANDA, respectively. We received no comments regarding these proposed revisions, and we are finalizing these provisions without change.

V.M. Date of Approval of a 505(b)(2) Application or ANDA (§ 314.107)

V.M.1. General (§ 314.107(a))

We proposed to revise the general regulation that describes the ''effective date of approval'' of a 505(b)(2) application or ANDA and the date on which the approval of a 505(b)(2) application or ANDA ''becomes effective'' to simply refer to the date the 505(b)(2) application or ANDA ''is approved'' (see proposed § 314.107(a)). In the proposed rule, we explained that FDA does not issue approval letters with delayed effective dates. We received no comments on these revisions, and we are finalizing proposed § 314.107(a) without change.

V.M.2. Effect of Patent(s) on the Listed Drug (§ 314.107(b))

We proposed to revise the regulation that describes the effect of one or more patents on the listed drug(s) relied upon or the RLD on the timing of approval of a 505(b)(2) application or ANDA, respectively (see proposed § 314.107(b)). We proposed to clarify that an analysis is required for each relevant patent to determine the first possible date on which the 505(b)(2) application or ANDA can be approved based on the patent certification(s) and/or statement(s) submitted by the applicant (see proposed § 314.107(b)). We proposed that the 505(b)(2) application or ANDA may be eligible for approval on the last applicable date for all relevant patents listed in the Orange Book (see proposed § 314.107(b) and proposed deletion of § 314.107(b)(4)). In the proposed rule, we explained that an analysis of the effect of one or more patents on the timing of approval of a 505(b)(2) application or ANDA is made when the 505(b)(2) application or ANDA is otherwise eligible for approval. We received no comments on these revisions, and we are finalizing the introductory text of proposed § 314.107(b) with the IRTNTMA-related revisions described in section V.A.3.

V.M.2.a. *Timing of approval based on patent certification or statement (§ 314.107(b)(1)).* We proposed to describe the timing of approval of a 505(b)(2) application or ANDA based on the patent certification(s) and/or statement(s) submitted by the applicant for each relevant patent (see proposed § 314.107(b)(1)). We proposed to reorganize the regulation and describe the types of patent certifications or statements that would result in an immediate first possible date on which a 505(b)(2) application or ANDA may be approved (see proposed § 314.107(b)(1)(i) and (ii)) or in a delay in the first possible approval date until the date on which a patent will expire (see proposed § 314.107(b)(1)(iii)).

We proposed to clarify that, except as provided in § 314.107(b)(3) and (c), a 505(b)(2) application or ANDA containing a paragraph IV certification may be eligible for immediate approval only if the 45-day period provided for in section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act has expired (see proposed § 314.107(b)(1)(i)(C)). We also proposed to clarify that if a 505(b)(2) or ANDA applicant submits a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii), respectively, explaining that a method-of-use patent does not claim an indication or other condition of use for which the applicant is seeking approval and submits proposed labeling that appropriately carves out information related to the patented method of use, then the 505(b)(2) application or ANDA may be eligible for immediate approval (see proposed § 314.107(b)(1)(ii)). In the proposed rule, we explained that a listed patent may claim the drug substance and/or drug product in addition to one or more methods of use, and if the 505(b)(2) or ANDA applicant submitted a statement with respect to one or more methods of use and a paragraph IV certification with respect to the remaining claims, the first possible date on which the 505(b)(2) application or ANDA can be approved would be analyzed in accordance with proposed § 314.107(b)(1)(i)(C) and (b)(1)(ii).

We received no comments on proposed § 314.107(b)(1). However, we are revising § 314.107(b)(1)(ii) to expressly state that if a 505(b)(2) or ANDA applicant submits a paragraph IV certification for certain patent claims in addition to a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii) for other patent claims, a determination of the first possible date on which the 505(b)(2) application or ANDA can be approved also would require an analysis under § 314.107(b)(1)(i)(C). We also are making a minor editorial revision to proposed § 314.107(b)(1) to clarify that the provision applies to a 505(b)(2) application or an ANDA.

V.M.2.b. *Patent information filed after submission of 505(b)(2) application or ANDA (§ 314.107(b)(2)).* We proposed to clarify the effect of patent information filed after submission of a 505(b)(2) application or ANDA on the timing of approval of the 505(b)(2) application or ANDA (see proposed § 314.107(b)(2)). We proposed that if an NDA holder submits patent information for a listed drug after the date on which a 505(b)(2) application or ANDA relying upon such drug was submitted to FDA, the 505(b)(2) or ANDA applicant must comply with the requirements of §§ 314.50(i)(4) and (i)(6) and 314.94(a)(12)(vi) and (a)(12)(viii) regarding amendment of its patent certification or statement. We also proposed that if the 505(b)(2) or ANDA applicant submits an amendment containing a paragraph IV certification to a newly listed patent, the 505(b)(2) application or ANDA may be approved immediately upon the submission of an amendment containing documentation that the NDA holder and each patent owner have received notice of the paragraph IV certification, if the 505(b)(2) application or ANDA is otherwise eligible for approval (see proposed § 314.107(b)(2)). We proposed that there is no need to delay approval until the expiration of the 45-day period described in section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act because a 30-month stay of approval is not available in these circumstances.

We received no comments on these revisions. However, we are revising § 314.107(b)(2) to clarify that a 505(b)(2) or ANDA applicant must comply with the regulatory requirements regarding ''submission of an appropriate patent certification or statement'' to a newly listed patent rather than an ''amendment of its patent certification or statement'' because the latter phrase may incorrectly suggest a change to an existing patent certification or statement, which would not exist in the case of a newly listed patent. We are making conforming revisions to §§ 314.50(i)(4) and 314.94(a)(12)(vi).

V.M.2.c. *Disposition of patent litigation: Approval upon expiration of 30-month stay or 7½ years from date of listed drug approval (§ 314.107(b)(3)(i)).* We proposed that a 30-month stay (or a delay in approval for a 7½-year period where applicable) would be available only when the patent owner or exclusive patent licensee initiates a patent infringement action within the statutory timeframe in response to notice of a paragraph IV certification to a patent submitted to FDA before the date on which the 505(b)(2) application or ANDA was submitted (see proposed § 314.107(b)(3)(i)(A) and section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act). We proposed to clarify that a 30-month stay (or 7½ years where applicable) begins on the later of the date of receipt of the notice of paragraph IV certification by any owner of the listed patent, the NDA holder who is an exclusive patent licensee, or its representative(s) (see proposed § 314.107(b)(3)(i)(A)). In the proposed rule, we noted that a period of pediatric

exclusivity under section 505A of the FD&C Act also may affect the timing of approval of a 505(b)(2) application or ANDA in the circumstances described in proposed § 314.107(b)(3) (see 80 FR 6802 at 6863).

In the following paragraphs, we discuss a comment on proposed § 314.107(b)(3)(i). After considering this comment, we are finalizing proposed § 314.107(b)(3)(i) with the IRTNMTA-related revisions described in section V.A.3 and a revision to conform with § 314.107(f)(1) and clarify that a 30-month stay begins on the later of the date of receipt of the notice of paragraph IV certification by any owner of the listed patent, the NDA holder, or its representative(s). We also are making a technical amendment to the paragraph heading described in section V.P.3.

(Comment 53) One comment recommended that FDA revise § 314.107(b)(3)(i) to accept any reason a court provides for reducing the 30-month stay, and not solely an extension or reduction of the 30-month stay because of a failure of the applicant or patent owner to cooperate reasonably in expediting the action.

(Response 53) We agree that if, before the expiration of the stay, the court enters an order requiring the 30-month or 7½-year period to be terminated, the 505(b)(2) application or ANDA may be approved in accordance with the court's order (see § 314.107(b)(3)(vii) and section V.M.2.i). However, we are not revising the regulation because § 314.107(b)(3)(vii) adequately addresses the concern described in the comment by providing for termination of the 30-month stay if the court enters an order requiring the 30-month stay to be terminated. Our regulation governing this scenario is consistent with the statutory purpose of the stay, which allows time for claims of patent infringement to be litigated prior to approval of the potentially infringing drug product.

V.M.2.d. *Federal district court decision of invalidity, unenforceability, or non-infringement (§ 314.107(b)(3)(ii)).* The MMA amended section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act to describe certain types of court decisions in patent litigation that will terminate a 30-month stay (or 7½ years where applicable) and lead to approval of a 505(b)(2) application or ANDA that is otherwise eligible for approval. We proposed to revise our regulations to implement section 505(c)(3)(C)(i) and (j)(5)(B)(iii)(I) of the FD&C Act by providing that if, before the expiration of the 30-month stay (or 7½ years where applicable), the district court decides that the patent is invalid, unenforceable, or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the 505(b)(2) application or ANDA may be approved on the date on which the court enters judgment reflecting the decision pursuant to Federal Rule of Civil Procedure (Fed. R. Civ. P.) Rule 58, or the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed (see proposed § 314.107(b)(3)(ii)). We also proposed that a Federal district court decision that the applicable patent is unenforceable (for example, because of inequitable conduct in patent prosecution) would terminate a 30-month stay or 7½ years where applicable (see proposed § 314.107(b)(3)(ii)).

We received no comments on these proposed revisions. We are finalizing proposed § 314.107(b)(3)(ii) with a technical amendment to add the term ''unenforceable'' to § 314.107(b)(3)(ii)(B) for consistency and completeness.

V.M.2.e. *Appeal of Federal district court judgment of infringement (§ 314.107(b)(3)(iii)).* We proposed to revise our regulations to implement section 505(c)(3)(C)(ii)(I) and (j)(5)(B)(iii)(II)(aa) of the FD&C Act by providing that if, before the expiration of the 30-month stay (or 7½ years where applicable), the Federal district court decides that the patent has been infringed and the judgment is appealed, the 505(b)(2) application or ANDA may be approved on: (1) The date on which the mandate is issued by the court of appeals entering judgment that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity) or (2) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed.

We received no comments on these proposed revisions. We are finalizing proposed § 314.107(b)(3)(iii) with technical amendments to add the term ''unenforceable'' to § 314.107(b)(3)(iii)(A) and (B) for consistency and completeness. We are also deleting the parenthetical reference to a substantive determination by a Federal district court that there is no cause of action for patent invalidity for the reason discussed in section V.M.2.d.

V.M.2.f. *Affirmation or non-appeal of Federal district court judgment of infringement (§ 314.107(b)(3)(iv)).* We proposed to establish a regulation that would implement section 505(c)(3)(C)(ii)(II) and (j)(5)(B)(iii)(II)(bb) of the FD&C Act by providing that if, before the expiration of the 30-month stay (or 7½ years where applicable), the Federal district court decides that the patent that is the subject of the paragraph IV certification is infringed and this judgment is not appealed or is affirmed on appeal, the 505(b)(2) application or ANDA may be approved no earlier than the date specified by the district court in an order under 35 U.S.C. 271(e)(4)(A) (see proposed § 314.107(b)(3)(iv)). We proposed to clarify that the 505(b)(2) application or ANDA may be approved no earlier than the date specified by the district court in a 35 U.S.C. 271(e)(4)(A) order because the order may not take into account any other unexpired patents or unexpired exclusivity (or deficiencies in the application) that would delay approval of the 505(b)(2) application or ANDA beyond the expiration date of the infringed patent (see proposed § 314.107(b)(3)(iv)). In the following paragraphs, we discuss a comment related to this provision. After considering this comment, we are finalizing proposed § 314.107(b)(3)(iv) without change.

(Comment 54) One comment recommends that FDA revise § 314.107(b)(3) to provide that FDA will not approve a pending 505(b)(2) application or ANDA if a district court decides after the 30-month stay or 7½-year period has expired that the patent that is the subject of the paragraph IV certification is infringed. The comment expresses concern that the regulatory focus on court decisions before the expiration of the 30-month stay or 7½-year period may be interpreted to mean that FDA can approve a 505(b)(2) application or ANDA if a district court decides after the 30-month stay or 7½-year period has expired that the proposed product would infringe a listed patent.

(Response 54) We decline to revise § 314.107(b)(3) as suggested because other regulations address the concern described in the comment (see, *e.g.,* §§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A) (requiring a 505(b)(2) or ANDA applicant to amend a previously submitted paragraph IV certification after a finding of patent infringement)). We are enhancing our regulations to impose a duty on 505(b)(2) and ANDA applicants to notify FDA of any court judgment, settlement order, or consent decree regarding a patent described in § 314.107(b)(3) (see § 314.107(e)(1)(i); see also § 314.107(e)(1)(ii)). We are also requiring an applicant to submit a copy

of any court order under 35 U.S.C. 271(e)(4)(A) providing that the 505(b)(2) application or ANDA may be approved no earlier than the date specified in the order, irrespective of whether the injunction relates to a patent described in § 314.107(b)(3), within 14 days of the court's entry of the order (see § 314.107(e)(1)(vi)). In addition, the Agency routinely contacts an applicant after the 30-month stay (or 7½ years where applicable) has expired to confirm the status of any pending litigation prior to an action on the 505(b)(2) application or ANDA.

V.M.2.g. *Grant of preliminary injunction by Federal district court (§ 314.107(b)(3)(v)).* We proposed to revise our regulations to implement section 505(c)(3)(C)(iii) and (iv) and (j)(5)(B)(iii)(III) and (IV) of the FD&C Act by providing that if a preliminary injunction is entered before the expiration of the 30-month stay (or 7½ years where applicable), the stay of approval would be extended until the court decides the issues of patent infringement and validity. In the proposed rule, we explained that proposed § 314.107(b)(3)(v) cross-references the applicable paragraph of § 314.107(b)(3) that would address the timing of approval of the 505(b)(2) application or ANDA based on the court's decision regarding patent validity and infringement. We proposed that if the court later decides that the patent is invalid, unenforceable, or not infringed, the 505(b)(2) application or ANDA may be approved as provided in § 314.107(b)(3)(iii) or (iv), whichever is applicable (see proposed § 314.107(b)(3)(v)). In addition, we proposed to clarify that the court referred to in § 314.107(b)(3)(v) is the Federal district court hearing the patent infringement action.

In the following paragraphs, we discuss two comments on the timing of approval of a 505(b)(2) application or ANDA after a preliminary injunction has been entered. After considering these comments, we are revising § 314.107(b)(3)(v) to more clearly describe the timing of approval of a 505(b)(2) application or ANDA when a preliminary injunction is entered before the expiration of a 30-month stay (or 7½ years where applicable) and to cross-reference the applicable paragraphs of § 314.107(b)(3). We are redesignating a portion of proposed § 314.107(b)(3)(v) as paragraph (b)(3)(v)(A) and adding paragraph (b)(3)(v)(B) to implement section 505(c)(3)(C)(iv) and (j)(5)(B)(iii)(IV) of the FD&C Act. With these revisions, the regulation provides:

- If a preliminary injunction is entered before the expiration of a 30-month stay (or 7½ years where applicable) and the Federal district court later decides that the patent is invalid, unenforceable, or not infringed, the 505(b)(2) application or ANDA may be approved as provided in § 314.107(b)(3)(ii) (see § 314.107(b)(3)(v)(A) and section 505(c)(3)(C)(iii) and (j)(5)(B)(iii)(III) of the FD&C Act).
- If a preliminary injunction is entered before the expiration of a 30-month stay (or 7½ years where applicable) and the Federal district court later decides that the patent is infringed, the 505(b)(2) application or ANDA may be approved as provided in § 314.107(b)(3)(iii) or (iv), whichever is applicable (see § 314.107(b)(3)(v)(B) and section 505(c)(3)(C)(iv) and (j)(5)(B)(iii)(IV) of the FD&C Act).

(Comment 55) One comment asserts that if a preliminary injunction is entered before the expiration of the 30-month stay, the stay should not be extended until the court decides the issues of patent infringement and validity because the preliminary injunction serves the purpose of the stay. The comment recommends that FDA issue a final approval of the 505(b)(2) application or ANDA (if otherwise eligible for approval) after the 30-month stay expires so that the product can be marketed without delay at such time as the injunction is lifted.

(Response 55) We disagree with the comment. If a preliminary injunction is entered before the expiration of the 30-month stay (or 7½ years where applicable), FDA interprets section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act to require an extension of the stay until the court decides the issues of patent infringement and validity because all of the outcomes described in the statute presume that approval will not occur until a later date.

(Comment 56) One comment requests that FDA revise the regulation to clarify the timing of approval if the district court enters a preliminary injunction after the 30-month stay expires. The comment recommends that FDA not approve a pending 505(b)(2) application or ANDA in this scenario unless the court later decides the patent is invalid, unenforceable, or not infringed. The comment also asserts that FDA's view that a preliminary injunction entered before the expiration of the 30-month stay would extend the stay until the court decides the issues of patent infringement and validity suggests that the issuance of a preliminary injunction after expiry of the 30-month or 7½-year period, combined with a district court finding of infringement, stays approval through at least the appeal.

(Response 56) We decline to adopt the recommendations in the comment. It is unnecessary for FDA to establish a regulation that addresses the timing of approval of a 505(b)(2) application or ANDA if a district court enters a preliminary injunction after the 30-month stay (or 7½-year period where applicable) has expired. If a party to a patent infringement action involving a patent described in § 314.107(b)(3) seeks to ensure that a 505(b)(2) application or ANDA is not approved while the litigation is pending, the party may request a preliminary injunction before the 30-month stay (or 7½-year period where applicable) expires. If a court enters a preliminary injunction after the 30-month stay (or 7½-year period where applicable) has expired, parties should ensure that the court specifies the duration and effect of the injunction.

(Comment 57) One comment suggests that if a court requests an applicant to voluntarily agree not to begin marketing the drug product or to provide pre-launch notice instead of issuing a preliminary injunction, FDA should treat these agreements as equivalent to a preliminary injunction and similarly extend the 30-month stay or 7½-year period.

(Response 57) We decline to adopt this suggestion. The FD&C Act provides that if the district court grants a preliminary injunction before the expiration of the 30-month stay (or 7½ years where applicable) to preserve the status quo until the court decides the issues of patent infringement and validity, the stay must be extended until the applicable date described in section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act. A voluntary agreement not to begin marketing the drug product or to provide pre-launch notice does not fall within this statutory exception to the termination of the stay at the end of the 30-month period (or 7½ year-period where applicable). Accordingly, we do not consider such agreements to be equivalent to a preliminary injunction for purposes of extending the stay. Moreover, it is unnecessary for the Agency to address these circumstances through regulation because the parties to the litigation can specify the desired terms of the agreement.

V.M.2.h. *Written consent to approval by patent owner or exclusive patent licensee (§ 314.107(b)(3)(vi)).* We proposed to clarify that if the patent owner or exclusive patent licensee (or their representatives) agreed in writing that the 505(b)(2) application or ANDA may be approved, the 30-month stay (or 7½ years where applicable) would be terminated and the approval may be granted on or after the date of the

consent (see proposed § 314.107(b)(3)(vi)). In the proposed rule, we noted that this scenario may arise, for example, if settlement of the patent litigation results in a license to the 505(b)(2) or ANDA applicant. One comment agrees with the addition of this provision because it expressly permits the party that receives the benefit of the statutory 30-month stay to waive that benefit. We agree with the comment and we are finalizing proposed § 314.107(b)(3)(vi) without change.

V.M.2.i. *Court order terminating 30-month or 7½-year period (§ 314.107(b)(3)(vii)).* We proposed to clarify that if a court enters an order requiring the termination of the 30-month stay (or 7½ years where applicable), the 505(b)(2) application or ANDA, if otherwise eligible for approval, may be approved in accordance with the court order (see proposed § 314.107(b)(3)(vii)). We received no comments on this provision, and we are finalizing proposed § 314.107(b)(3)(vii) without change.

V.M.2.j. *Court order of dismissal without a finding of infringement (§ 314.107(b)(3)(viii)).* We proposed to codify FDA's policy that a Federal district court's entry of an order of dismissal, with or without prejudice, of patent infringement litigation that was timely initiated in response to the 505(b)(2) or ANDA applicant's notice of a paragraph IV certification will terminate the 30-month period (or 7½ years where applicable) if such order does not state a finding of patent infringement (see proposed § 314.107(b)(3)(viii)).

In the following paragraphs, we discuss two comments on proposed § 314.107(b)(3)(viii). After considering these comments, we are revising § 314.107(b)(3)(viii) to clarify that the 30-month period (or 7½ years where applicable) will be terminated if the court(s) enter(s) an order of dismissal without a finding of infringement in each pending suit for patent infringement brought within 45 days of receipt of the notice of paragraph IV certification sent by the 505(b)(2) or ANDA applicant.

(Comment 58) One comment opines that proposed § 314.107(b)(3)(viii) should be withdrawn because the statute does not specify that an order of dismissal without a finding of infringement will terminate a 30-month stay (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act).

(Response 58) We decline to withdraw our proposal. The MMA's amendments to the FD&C Act clarify the timing of approval of a 505(b)(2) application or ANDA, respectively, in relation to a settlement order or consent decree stating that the patent that is the subject of the paragraph IV certification is invalid or not infringed (see section 505(c)(3)(C)(i)(II), (c)(3)(C)(ii)(I)(bb), (j)(5)(B)(iii)(I)(bb), and (j)(5)(B)(iii)(II)(aa)(BB) of the FD&C Act). However, the MMA does not address whether a 30-month stay may be terminated and a 505(b)(2) application or ANDA may be approved if the court enters an order of dismissal without a finding of patent infringement. Because this issue was not addressed by Congress, the Agency is using its authority to establish rules for the efficient enforcement of the FD&C Act to clarify the effect of a Federal district court's entry of an order of dismissal without a finding of infringement on a 30-month stay of approval. The Agency's approach is consistent with the statutory scheme because it avoids unwarranted delays in approval of a 505(b)(2) application or ANDA while protecting innovator intellectual property rights. As we explained in the proposed rule, it is appropriate that a 30-month stay be terminated under these circumstances because the statutory purpose of the stay is to allow time for claims of patent infringement to be litigated prior to approval of the potentially infringing drug product. If the patent owner or exclusive patent licensee dismisses the patent infringement action on terms that the court considers proper (see Fed. R. Civ. P. Rule 41(a)(2)), then there should be no further delay of approval of a 505(b)(2) application or ANDA otherwise eligible for approval.

(Comment 59) One comment recommends that FDA revise proposed § 314.107(b)(3)(viii) to exclude dismissals that do not terminate all timely filed litigation with respect to the patent(s) in suit. The comment explains that parallel suits for patent infringement may be filed in different Federal district courts within the 45-day period described in section 505(j)(5)(B)(iii) of the FD&C Act, and one or more suits may be dismissed because of lack of jurisdiction or other reasons. The comment maintains that the 30-month stay should remain in effect if one of multiple patent infringement actions filed in response to notice of a paragraph IV certification is dismissed while at least one of the timely filed lawsuits continues to be litigated.

(Response 59) We agree that the 30-month stay should remain in effect if a patent infringement action that was timely filed in response to a paragraph IV certification continues to be litigated after the dismissal of a parallel action. We are revising § 314.107(b)(3)(viii) to clarify that the 30-month period (or 7½ years where applicable) will be terminated if the court(s) enter(s) an order of dismissal without a finding of infringement in each pending suit for patent infringement brought within 45 days of receipt of the notice of paragraph IV certification sent by the 505(b)(2) or ANDA applicant.

(Comment 60) One comment recommends that FDA revise proposed § 314.107(b)(3)(viii) to provide that if the court enters an order of dismissal without a finding of patent infringement based on an agreement not to make or sell the drug until a specified future date, the stay should continue until the date provided in the agreement.

(Response 60) We decline to adopt this suggestion. If the court(s) enter(s) an order of dismissal without a finding of infringement in each pending suit for patent infringement brought within 45 days of receipt of the notice of paragraph IV certification sent by the 505(b)(2) or ANDA applicant, FDA may approve the 505(b)(2) application or ANDA on or after the date of the order. If a 505(b)(2) or ANDA applicant has entered into an agreement not to make or sell the drug until a specified future date and the 505(b)(2) application or ANDA receives final approval, the applicant can choose not to make or sell the product until the specified date.

V.M.3. Timing of Approval of Subsequent ANDA (§ 314.107(c))

We proposed to revise § 314.107(c) to remove provisions that have been superseded by the FD&C Act as revised by the MMA and to generally conform with the FD&C Act. We proposed to revise § 314.107(c)(1) to incorporate the statutory term ''first applicant'' and to distinguish a ''first applicant'' from a ''subsequent applicant'' (see section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act and proposed § 314.3(b)). We proposed that an ANDA has been submitted by a subsequent applicant if the ANDA has not been submitted by a first applicant and contains a paragraph IV certification to a relevant patent that has been listed for the drug product for which a first applicant has submitted an ANDA (see proposed § 314.107(c)(1)). We proposed that a subsequent applicant's ANDA will not be approved during the period when any first applicant for the drug product is eligible for 180-day exclusivity or during the 180-day exclusivity period of any first applicant (see proposed § 314.107(c)(1) and section 505(j)(5)(B)(iv)(I) of the FD&C Act).

We proposed to delete the definition of the ''applicant submitting the first application'' in existing § 314.107(c)(2) because it was superseded by the statutory definition of ''first applicant'' added by the MMA. We also proposed to delete § 314.107(c)(3), which described the potential consequences of a first applicant's failure to actively pursue approval of its ANDA (see section 505(j)(5)(D) of the FD&C Act).

We proposed to revise § 314.107(c)(4) (redesignated as proposed § 314.107(c)(2)) to conform with the statutory change to the event that triggers the start of the 180-day exclusivity period for a first applicant (see section 505(j)(5)(B)(iv)(I) of the FD&C Act). Given that the 180-day exclusivity period begins on the date of the first commercial marketing of the drug product (including the commercial marketing of the listed drug) by any first applicant, we proposed to require a first applicant to submit correspondence to its ANDA notifying FDA within 30 days of the date of first commercial marketing of the drug product (see proposed § 314.107(c)(2) and section 505(j)(5)(B)(iv)(I) of the FD&C Act). If the first applicant does not notify FDA within this timeframe, we proposed to deem the date of first commercial marketing to be the date of the ANDA's approval. In the proposed rule, we noted that this may have the effect of shortening the 180-day period of exclusivity in a manner similar to existing § 314.107(c)(4). We also proposed to remove the description of ''commercial marketing'' from § 314.107(c)(4) because we proposed to define ''commercial marketing'' in proposed § 314.3(b) with certain modifications to the scope of the exclusion for transfer of the drug product for reasons other than sale.

In the following paragraphs, we discuss three comments on proposed § 314.107(c). After considering these comments, we are finalizing proposed § 314.107(c)(1) without change and we are finalizing proposed § 314.107(c)(2) with a technical amendment to include a reference to first commercial marketing of the RLD for consistency with section 505(j)(5)(B)(iv)(I) of the FD&C Act. We also are making an editorial correction to remove the introductory phrase in § 314.107(c)(2) referring to § 314.107(c)(1). We are not finalizing our proposal to delete § 314.107(c)(3) because we want to retain flexibility to ensure that approval of ANDAs of subsequent applicants is not blocked, for example, by a first applicant that is nonresponsive to repeated inquiries from the Agency regarding its ANDA. In addition, we are making clarifying revisions to this provision. As revised, § 314.107(c)(3) explains that if FDA concludes that a first applicant is not actively pursuing approval of its ANDA, FDA may immediately approve an ANDA(s) of a subsequent applicant(s) if the ANDA(s) is otherwise eligible for approval.

(Comment 61) One comment asserts that FDA's proposal to deem the date of first commercial marketing to be the date of the drug product's approval if a first applicant fails to timely notify FDA is inconsistent with the statute, FDA's proposed and existing definitions of ''commercial marketing,'' and the predecessor regulation at § 314.107(c)(3), because the product was not actually marketed on the deemed date. Another comment maintains that FDA's proposal to deem the date of first commercial marketing to be the date of the drug product's approval if a first applicant fails to timely notify FDA is a penalty that is not warranted by the statutory change in the commercial marketing trigger of the 180-day exclusivity period.

(Response 61) We do not find these comments persuasive. Section 505(j)(5)(B)(iv)(I) of the FD&C Act provides that the period of 180-day exclusivity will begin on the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant. This commercial marketing trigger differs from the version of section 505(j)(5)(B)(iv)(I) in effect prior to enactment of the MMA, which provided that the 180-day exclusivity period will begin on the earlier of two events, one of which was the date the Secretary receives notice from the applicant of the first commercial marketing of the drug eligible for 180-day exclusivity. Based on the change in the commercial marketing trigger from the date on which FDA receives notice from the applicant of the first commercial marketing to the date of the first commercial marketing of the drug, we are requiring the first applicant to notify FDA within 30 days of the date of first commercial marketing. This requirement is intended to facilitate the efficient enforcement of the FD&C Act and provide FDA with adequate notice to inform the timing of approval for ANDAs submitted by subsequent applicants. If a first applicant does not notify FDA within this timeframe, we will deem the date of first commercial marketing to be the date of the ANDA's approval. This consequence of a first applicant's failure to provide timely notification to FDA is similar to the consequence described in the predecessor regulation at § 314.107(c)(4), which provided that if an applicant does not promptly notify FDA of commercial marketing, the effective date of approval shall be deemed to be the date of the commencement of first commercial marketing. We expect that the regulation will encourage first applicants to provide timely notification to FDA. Given that the date of notification is within a first applicant's control, we expect that there will be few instances in which there is a need to deem the date of first commercial marketing to be the date of the ANDA's approval.

(Comment 62) One comment expresses concern that FDA may deem the date of first commercial marketing to be the date of the drug product's approval if a first applicant does not launch its drug product within 30 days after ANDA approval. The comment proposes that FDA require a first applicant to notify FDA if the applicant will not launch the drug product within 30 days after ANDA approval, but intends to launch the drug product within 75 days after ANDA approval.

(Response 62) We decline to adopt this suggestion because it is unnecessary. FDA would only deem the date of first commercial marketing to be the date of the ANDA's approval if a first applicant began commercial marketing of the drug product described in the ANDA or of the reference listed drug and failed to notify FDA within 30 days of the first commercial marketing (see § 314.107(c)(2)). This provision would not apply if commercial marketing had not yet commenced. FDA's requirement for a first applicant to timely notify the Agency of the date of first commercial marketing is intended to facilitate implementation of the statutory change in the commercial marketing trigger of the 180-day exclusivity period (section 505(j)(5)(B)(iv)(I) of the FD&C Act). This notification requirement is unrelated to the statutory conditions under which a first applicant would forfeit the 180-day exclusivity period for failure to market the product (see section 505(j)(5)(D)(i)(I) of the FD&C Act). We will determine whether additional rulemaking related to 180-day exclusivity is necessary in the future.

V.M.4. Delay of Approval Due to Exclusivity (§ 314.107(d))

We proposed to clarify that approval of a 505(b)(2) application or ANDA may be delayed by orphan drug exclusivity under 21 CFR 316.31 or pediatric exclusivity under section 505A of the FD&C Act, in addition to the exclusivities described in § 314.108 (see proposed § 314.107(d)).

In section V.A.7, we discuss a comment on proposed § 314.107(d) (see Comment 8). After considering this comment, we are revising § 314.107(d) to indicate that approval of a 505(b)(2) application or ANDA also may be delayed by a period of exclusivity for the listed drug under section 505E of the FD&C Act. We are also making a technical edit to refer to section 527 of the FD&C Act in the context of a delay in approval of a 505(b)(2) application or ANDA because of orphan drug exclusivity.

V.M.5. Notification of Court Actions or Written Consent to Approval (§ 314.107(e))

We proposed to revise § 314.107(e) to expand the scope of documentation that an applicant must submit to FDA regarding court actions and settlements related to patents that may affect the timing of approval of a 505(b)(2) application or ANDA. We proposed to require a 505(b)(2) or ANDA applicant to submit a copy of any judgment by the court (Federal district court or mandate of the court of appeals) finding a patent described in § 314.107(b)(3) invalid, unenforceable, or not infringed, or finding the patent valid and infringed (see proposed § 314.107(e)(1)(i)). We also proposed to require a 505(b)(2) or ANDA applicant to submit to FDA a copy of specified documented agreements and court actions other than judgments to facilitate FDA's administration of the FD&C Act (see § 314.107(e)(1)(i) through (vi)).

We explained that the proposed requirement to submit a copy of any documented agreement described in § 314.107(b)(3)(vi) would require submission of written documentation that the parties have entered into a settlement that terminated the patent infringement litigation, but would not require applicants to send copies of the actual settlement agreement to FDA (see proposed § 314.107(e)(1)(iv)). To ensure timely notification to FDA, we proposed to require a 505(b)(2) or ANDA applicant to submit all required information to the appropriate division in OND or to OGD, within 14 calendar days of the date of entry by the court, the date of appeal or expiration of the time for appeal, or the date of documented agreement, as applicable (see proposed § 314.107(e)(2)).

In the following paragraphs, we discuss a comment on proposed § 314.107(e)(1)(iv). After considering this comment, we are revising § 314.107(e)(1)(iv) to require submission of a copy of any ''written consent to approval'' by the patent owner or exclusive patent licensee, and we are making a conforming revision to § 314.107(e)(2) and to the paragraph heading for § 314.107(e). We also are clarifying that a copy of any order entered by the court terminating the 30-month or 7½-year period includes an order described in § 314.107(b)(3)(vii) and (viii). Finally, for administrative convenience, we are revising § 314.107(e)(2) to provide that all information required by § 314.107(e)(1) must be sent to the applicant's NDA or ANDA rather than to OGD or the appropriate division in OND.

(Comment 63) One comment agrees with FDA's proposal to require submission of written documentation that the parties have entered into a settlement that has terminated the patent infringement litigation, and recommends that FDA revise proposed § 314.107(e)(1)(iv) to expressly state that a ''documented agreement'' does not refer to the settlement agreement, and that a copy of the actual settlement agreement need not be submitted. The comment also requests that FDA clarify the content of the documentation that should be submitted.

(Response 63) We agree that the proposal to require applicants to submit a copy of any ''documented agreement'' has been the source of confusion, notwithstanding the statement in the proposed rule that applicants are not required to send copies of the actual settlement agreement to FDA. We are revising § 314.107(e)(1)(iv) to require submission of a copy of any ''written consent to approval'' by the patent owner or exclusive patent licensee. This revision is intended to clarify the requested information and align with the text of § 314.107(b)(3)(vi). A letter to FDA from the patent owner(s) or exclusive patent licensee that provides consent to approval of the 505(b)(2) application or ANDA any time on or after the date of consent would be acceptable. Although FDA does not require a copy of the actual settlement agreement, we note that generic drug applicants are required to file certain agreements with the FTC (see section 1112 of the MMA).

V.M.6. Computation of the 45-Day Time Clock (§ 314.107(f))

We proposed to revise § 314.107(f)(1) and (2) to clarify the computation of the 45-day period after receipt of notice of paragraph IV certification and to enhance the requirements for notifying FDA of any legal action filed within this timeframe. We proposed to add § 314.107(f)(2)(iii) to clarify that a 505(b)(2) application or ANDA may be approved upon expiration of the 45-day period (if the 505(b)(2) or ANDA applicant confirms that a legal action for patent infringement has not been filed within the 45-day period) or upon completion of FDA's review of the 505(b)(2) application or ANDA, whichever is later. We also proposed to revise § 314.107(f)(3) to expressly permit a representative of the patent owner or NDA holder who is an exclusive patent licensee to waive the opportunity to file a patent infringement action within the 45-day period.

We received no comments regarding these proposed revisions, and we are finalizing proposed § 314.107(f) without change, except for the technical amendments described in section V.P.5 regarding the location to which the notification must be sent.

V.M.7. Conversion of Approval to Tentative Approval (§ 314.107(g))

We proposed to add § 314.107(g) to clarify that if FDA issues an approval letter in error or a court enters an order requiring that the date of approval be delayed for an already approved 505(b)(2) application or ANDA, FDA will convert the approval to a tentative approval if appropriate. In the following paragraphs, we discuss a comment on this proposed provision. After considering this comment, we are finalizing proposed § 314.107(g) without change.

(Comment 64) One comment recommends that FDA remove the qualifier ''if appropriate'' from proposed § 314.107(g). The comment also requests that FDA clarify that ''court'' refers to either a district court or an appellate court for consistency with *Mylan Labs., Inc.* v. *Thompson,* 389 F.3d 1272 (D.C. Cir. 2004).

(Response 64) FDA declines to adopt the suggestion to remove the qualifier ''if appropriate'' from proposed § 314.107(g) because there are circumstances in which it may not be appropriate to convert an approval to a tentative approval (*e.g.,* a stay of the district court's order pending appeal). Moreover, the qualifier ''if appropriate'' also modifies FDA's issuance of an approval letter in error, and the appropriateness of conversion to tentative approval may depend on a variety of factors. If either a district court or appellate court enters an order requiring that the date of approval of an already approved 505(b)(2) application or ANDA be delayed, FDA will convert the approval to a tentative approval if appropriate.

V.N. Assessing Bioavailability and Bioequivalence for Drugs Not Intended To Be Absorbed Into the Bloodstream (§ 320.23)

We proposed to revise § 320.23 to reflect the MMA's amendments to section 505(j)(8) of the FD&C Act, which permit use of scientifically valid methods for assessing bioavailability and bioequivalence for drugs that are not intended to be absorbed into the bloodstream and essentially codify our existing practice. We received no comments regarding these proposed revisions, and we are finalizing proposed § 320.23 without change.

V.O. Miscellaneous

We proposed several clarifying revisions and editorial changes throughout the sections of parts 314 and 320 that were the subject of the proposed rule. These changes were intended to promote consistency throughout our regulations, incorporate ''plain language,'' employ grammatically correct phrasing, and otherwise clarify the text of these regulations. We also proposed certain revisions to provisions that contemplated the submission of paper to facilitate the transition to electronic submissions in the future. We did not receive any comments on these proposed revisions, and we are finalizing them without change.

V.P. Technical Amendments

We are making several technical amendments in the sections of parts 314 and 320 that are the subject of this rulemaking. These changes are intended to promote clarity and consistency throughout our regulations and correct certain outdated or incorrect information. Examples of revisions that are not otherwise described are provided in sections V.P.1 through V.P.6.

V.P.1. Consistent Use of Defined Terms

We are replacing the terms ''application'' and ''abbreviated application'' with the commonly used abbreviations ''NDA'' and/or ''ANDA,'' as appropriate, in the following sections: §§ 314.3(b) (definitions of ''original application or original NDA'' and ''tentative approval''); 314.50(h); 314.53(b)(1); 314.93(b); 314.94(a)(3), (a)(12)(i)(A)(*4*)(*i*), (a)(12)(ii), (a)(12)(viii)(B), and introductory text to § 314.94; 314.95(d)(1) and (f); 314.97(a); 314.107(b)(4) and (f)(3); and 314.127(a)(2) and (a)(8)(ii)(B) and (C).

We are replacing the term ''act'' with ''Federal Food, Drug, and Cosmetic Act'' in the following sections: §§ 314.50(d); 314.60(b)(1) and (4), (c)(1)(i), and (c)(2); 314.93(d)(3) and (e)(1)(iii)(C); 314.94(a)(3)(ii), (a)(5)(ii)(A), (a)(7)(ii)(C), and (a)(8)(iv); 314.125(a) and (b)(2), (11), and (18); and 314.127(a)(3)(iii)(A)(*2*) and (a)(12).

We are defining ''Agency'' as an alternate term for ''FDA'' for clarity (see § 314.3(b)).

We are replacing references to the ''holder of [an or the] approved application'' with the defined term ''NDA holder'' in the following sections: §§ 314.50(i)(1)(i)(A)(*4*)(*ii*); 314.70(a)(2); and 314.94(a)(12)(i)(A)(*4*)(*ii*).

We are revising the proposed definition of ''resubmission'' in § 314.3(b) to clarify that the definition applies only in the context of a complete response letter (compare § 314.101(b)(3)(ii), which uses the term ''resubmit'' with a different meaning and in a different context).

We are replacing the term ''right of reference'' with the defined term ''right of reference or use'' in § 314.60(c)(1)(iii).

We are making an editorial correction to the proposed definition of ''therapeutic equivalents'' in § 314.3(b) to combine the sentences into a single-sentence definition to be consistent with the definition in the Orange Book. As revised, ''therapeutic equivalents'' are approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

We are replacing the reference to a ''use patent'' with the term ''method-of-use patent'' (see §§ 314.50(i)(1)(iii)(A) and (B), 314.52(a)(3), 314.53(e), 314.94(a)(12)(iii)(A) and (B), and 314.95(a)(3)).

V.P.2. Alignment of Certain Regulations for 505(b)(2) Applications and ANDAs

We are making conforming revisions between certain provisions in §§ 314.50 and 314.94 to align the requirements for 505(b)(2) applications and ANDAs and enhance clarity.

We are expressly providing, with respect to a 505(b)(2) applicant that amends its paragraph IV certification after a finding of patent infringement, that once an amendment for the change has been submitted, the 505(b)(2) application will no longer be considered to contain a paragraph IV certification to the patent (see § 314.50(i)(6)(i)). However, we explain that if a final decision finds the patent to be invalid and infringed, an amended certification is not required. This revision to § 314.50(i)(6)(i) corresponds to the parallel regulation for ANDAs in § 314.94(a)(12)(viii)(A) and clarifies the general statement in the introductory text of § 314.50(i)(6) regarding amended patent certifications for 505(b)(2) applications.

We are revising § 314.94(a)(12)(viii)(A) to expressly provide that, after a finding of patent infringement, an ANDA applicant must submit a paragraph III certification or, with respect to a method-of-use patent, the applicant may instead provide a statement under § 314.94(a)(12)(iii) if the applicant amends its ANDA such that the applicant is no longer seeking approval for a method of use claimed by the patent. This revision to § 314.94(a)(12)(viii)(A) corresponds to the parallel regulation for 505(b)(2) applications in § 314.50(i)(6)(i) and describes an acceptable approach under the statute and existing regulations.

We are revising §§ 314.50(i)(1)(i)(A)(*4*)(*ii*) and 314.94(a)(12)(i)(A)(*4*)(*ii*) to conform with §§ 314.52(a)(2) and 314.95(a)(2), respectively, and provide that if the NDA holder does not reside or maintain a place of business in the United States, notice of a paragraph IV certification must be sent to its attorney, agent, or other authorized official.

We are revising § 314.94(a)(12)(viii) to clarify that a patent certification or statement may be amended at any time ''before the approval of the ANDA,'' rather than ''before the date of approval of the ANDA'' for consistency with § 314.50(i)(6).

V.P.3. Technical Corrections to Regulatory Concepts

We are revising the definition of ''505(b)(2) application'' to clarify that it is an NDA for which ''at least some of'' the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (see § 314.3(b)).

We are replacing the term ''filed'' with ''submitted'' in the first sentence of § 314.50(i)(4)(ii) to use consistent terminology in this paragraph and to accurately describe FDA's longstanding practice. As revised, an applicant whose 505(b)(2) application is submitted after the NDA holder's untimely filing of patent information must submit an appropriate patent certification or statement as to that patent.

We are deleting the phrase ''or changed'' from §§ 314.50(i)(5) and 314.94(a)(12)(vii) because a 505(b)(2) or ANDA applicant must submit an appropriate patent certification or statement for changes to patent information that are timely filed. We also are changing ''each relevant patent''

to ''each listed patent'' in §§ 314.50(i)(5) and 314.94(a)(12)(vii) for clarity.

We are revising the titles of §§ 314.52 and 314.95 to clarify that these sections relate to a notice of certification of invalidity, unenforceability, or non-infringement of a patent, as reflected in the text of these sections and FDA's definition of a paragraph IV certification.

We are revising the paragraph headings of §§ 314.52(f) and 314.95(f) to change them from ''Approval'' to ''Forty-five day period after receipt of notice'' to more clearly describe the content of these sections. We are also revising §§ 314.52(f) and 314.95(f) to add the NDA holder's attorney, agent, or other authorized official as potential recipients of the 505(b)(2) or ANDA applicant's notice of paragraph IV certification for consistency with §§ 314.52(a)(2) and 314.95(a)(2).

We are changing ''a drug product'' to ''the drug product'' in § 314.53(b)(1) to clarify that for patents that claim a drug product, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA.

We are revising the description of required patent information for drug substance patents to clarify that information must include whether the patent claims ''a'' drug substance that is ''an'' active ingredient in the drug product described in the NDA or supplement to reflect submission of patent information on drug products that contain more than one active ingredient (see § 314.53(c)(2)(i)(M)(*1*) and (c)(2)(ii)(N)(*1*)).

We are deleting the phrase ''including a 505(b)(2) application'' in § 314.53(d)(1) because the provision refers to an original NDA, which describes ''stand-alone'' applications submitted under section 505(b)(1) of the FD&C Act and 505(b)(2) applications.

We are adding the word ''active'' to a parenthetical reference to ''ingredient'' for clarity and consistency with the regulations governing submission of patent information on drug substances (see § 314.53(d)(1)).

We are replacing a reference to the provisions regarding ''untimely filed patents'' with the phrase ''untimely filed patent information'' for consistency with the paragraph headings of §§ 314.50(i)(4) and 314.94(a)(12)(vi) (see § 314.53(d)(3)).

We are replacing a reference to a request to ''delist a patent'' with the phrase ''remove a patent from the list'' for clarity (see § 314.53(f)(2)(iv)).

We are replacing a reference to an ''NDA'' in § 314.60(a) with a reference to an ''NDA, supplement, or resubmission'' for clarity and consistency with the content of this regulation.

We are replacing the phrase ''the listed drug approved in the petition'' in § 314.93 with the phrase ''the listed drug referenced in the approved petition'' for accuracy (see § 314.94(a)(3)(i)).

We are revising the paragraph heading of § 314.94(a)(12)(i) to describe ''patents claiming drug substance, drug product, or method of use'' for clarity and consistency with the regulation.

We are deleting the word ''who'' in the phrase ''letter acknowledging receipt by the person who provided the notice'' because the letter described in § 314.95(e) must acknowledge receipt by the person who received the notice, not the person who provided the notice.

We are deleting the phrase ''for the active moiety'' in the phrase ''[s]ubmission of a 505(b)(2) application or an ANDA for the active moiety'' because applicants submit 505(b)(2) applications and ANDAs for drug products, not active moieties, and the restriction on submission is described in the cited statutory references (see § 314.101(e)(2)).

We are revising the paragraph heading of § 314.107(b)(3)(i) to refer to the date of ''listed drug approval'' rather than the ''reference product approval'' because a 505(b)(2) application or ANDA may rely on a listed drug approved under the FD&C Act.

We are revising § 314.94(a)(12)(viii)(B) to clarify that if removal of a patent from the list results in there being no patents listed for the listed drug identified in the ANDA, the applicant must submit an amended certification reflecting that there are ''no relevant patents,'' rather than ''no listed patents,'' to incorporate the terminology used in § 314.94(a)(12)(ii).

We are revising the reference to an approval that ''will become effective'' to an approval that ''will occur'' because the Agency no longer uses this terminology (see § 314.108(b)(3)).

V.P.4. Technical Corrections to Statutory or Regulatory References

We are correcting statutory and regulatory citations in the sections of part 314 and 320 that are the subject of this rulemaking, as illustrated by the following examples:

- Delete the reference to ''section 505 of the act'' as unnecessary in the context of an approved NDA (see § 314.70(a)(2));
- Correct the statutory reference to the definition of ''new drug'' in section 201(p) of the FD&C Act (21 U.S.C. 321(p)) (see § 314.93(d)(3));
- Change ''section 505(j)(4)(D)'' to ''section 505(j)(5)(F)'' of the FD&C Act to correctly cite the relevant exclusivity provision (see § 314.94(a)(3)(ii));
- Update the citation for the definition ''same drug product formulation'' from § 320.1(g) to § 314.3(b) to reflect the relocation of the definition (see § 314.94(a)(7)(i));
- Add a reference to § 314.94(a)(12)(iii) to align with text regarding an ANDA applicant's submission of an appropriate patent certification *or statement* (see § 314.94(a)(12)(i)(B) and (a)(12)(viii)(C)(*1*)(*ii*));
- Change ''section 505(j)(4)(B)(iii)'' to ''section 505(j)(5)(B)(iii)'' of the FD&C Act to correctly cite the statutory provision regarding the 45-day period after receipt of notice of a paragraph IV certification (see § 314.95(f)); and
- Revise § 314.105(a) regarding approval of an NDA to delete the reference to § 314.107(c), which only applies to ANDAs.

V.P.5. Changes to Location for Sending Information

We are revising §§ 314.52(a)(2) and 314.95(a)(2) to clarify that the name and address of the NDA holder or its attorney, agent, or authorized official may also be obtained by sending an electronic communication to the Orange Book staff. As revised, §§ 314.52(a)(2) and 314.95(a)(2) provide that this information may be obtained by sending a written or electronic communication to the Orange Book Staff, Office of Generic Drugs, 7620 Standish Pl., Rockville, MD 20855, or to the Orange Book Staff at the email address listed on the Agency's Web site at *http://www.fda.gov*.

We are revising § 314.53(c)(2)(i)(B) and (c)(2)(ii)(B) to request the NDA applicant's full address, phone number, and, if available, fax number and email address in addition to the applicant's name to facilitate communication.

We are revising § 314.107(f)(2) to clarify that notification of the filing of any legal action within 45 days of the receipt of notice of a paragraph IV certification must be sent by a 505(b)(2) applicant to its NDA (rather than to the appropriate OND Review Division) and must be sent by an ANDA applicant to its ANDA (rather than to OGD).

V.P.6. Grammatical Corrections

We are making certain revisions to correct or improve grammar or punctuation in the sections of parts 314 and 320 that are the subject of this rulemaking, as illustrated by the following examples:

• Change ''which'' to ''that'' (see §§ 314.50(i)(1)(i)(A)(*4*)(*ii*) and 314.95(a)(1));

• Change ''method of use patent'' to ''method-of-use patent'' (see §§ 314.50(i)(1)(iii) and 314.94(a)(12)(iii));

• Change ''[o]nce an amendment for the change in certification has been submitted'' to ''[o]nce an amendment is submitted to change the certification'' (see § 314.50(i)(6));

• Change ''will no longer be considered to be one containing'' to ''will no longer be considered to contain'' (see §§ 314.50(i)(6) and 314.94(a)(12)(viii)(A) and (B));

• Delete the word ''use'' in the phrase ''one or more methods of using the drug product for which use approval is being sought'' for clarity (see § 314.53(c)(2)(i)(O)(*1*));

• Change ''United States'' to ''U.S.'' (see § 314.53(c)(2)(ii)(H));

• Change ''shall'' to ''must'' as appropriate (see §§ 314.53(d)(1) and 314.94(a), (a)(1), (a)(12)(i)(A)(*4*)(*i*) and (*ii*), (b), and (d)(2));

• Change ''except that § 314.50(d)(1)(ii)(*c*) must contain'' to ''except that the [technical] section described in § 314.50(d)(1)(ii)(*c*) must contain'' or ''except that the information required under § 314.50(d)(1)(ii)(*c*) must contain'' for clarity (see §§ 314.54(a)(2) and 314.94(a)(9)(i));

• Change ''any bioavailability of bioequivalence testing'' to ''any bioavailability or bioequivalence testing'' to correct a typographical error (see § 314.94(a)(7)(ii));

• Change ''it'' to ''the study'' for clarity (see §§ 314.94(a)(7)(iii)(B) and 314.101(d)(6) and (7));

• Change ''amendment to § 314.94(a)(9)'' to ''amendment under § 314.94(a)(9)'' for clarity (see § 314.96(b));

• Change ''their representatives'' to ''its representative'' or ''its representative(s)'' (see §§ 314.94(a)(12)(i)(A)(*4*)(*ii*) and 314.107(f)(2)(ii) and (iii) and (f)(3));

• Delete the words ''is or'' from the phrase ''is or has been removed'' (see § 314.94(a)(12)(viii)(B)); and

• Add appropriate descriptors (*e.g.,* ''section'' and ''paragraph'') to modify statutory and regulatory references (see § 314.94(d)(2)).

VI. Effective Date

This final rule is effective December 5, 2016. The final rule applies to any new submission (including but not limited to an NDA or ANDA, an amendment or supplement (including any patent certifications or statements), submission of patent information and requests by the NDA holder to amend or withdraw a patent or patent information, submission of a new patent listing dispute, and notification of court actions or written consent to approval) received by FDA on or after the effective date. In addition, a person (including a 505(b)(2) or ANDA applicant) may submit a request under § 314.53(f)(1) for an NDA holder to confirm the accuracy or relevance of previously submitted patent information in light of requirements for submission of patent information on and after the effective date of this final rule.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because average costs per entity are small, and the regulatory requirement with the highest cost per instance would affect few if any of the smallest entities, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

Many provisions of this final rule codify current practice, but some elements will lead to changes that generate additional benefits and costs. Table 2 summarizes the benefits and costs of this final rule. The estimated annualized monetized benefits of this final rule are $215,247 at a 3 percent or 7 percent discount rate, while the estimated annualized monetized costs are $266,947 at a 3 percent discount rate and $275,925 at a 7 percent discount rate. We have also identified, but are unable to quantify, additional impacts from changes to submitted patent information.

TABLE 2—SUMMARY OF BENEFITS AND COSTS

	Benefits	Costs
One-time (Year 1) Cost for Reading the Rule	N/A	$466,450
Annually Recurring Compliance Costs or Savings (Years 1–10)	$215,247	213,858
Present Value at 3 Percent	1,836,098	2,277,116
Present Value at 7 Percent	1,511,803	1,937,983
Annualized Value at 3 Percent	215,247	266,947
Annualized Value at 7 Percent	215,247	275,925

The full analysis of economic impacts is available in the docket for this final rule (Ref. 2) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.31(a) and (g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

The final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. The estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Abbreviated New Drug Applications and 505(b)(2) Applications.

Description of Respondents: Respondents to this collection of information are NDA applicants (including 505(b)(2) applicants) and ANDA applicants, patent owners, and their representatives.

Burden Estimate: This final rule implements portions of Title XI of the MMA that pertain to a 505(b)(2) or ANDA applicant's provision of notice of paragraph IV certification to each patent owner and the NDA holder; the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved; submission of amendments and supplements to 505(b)(2) applications and ANDAs; and the types of bioavailability and bioequivalence data that can be used to support these applications. This final rule also amends certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act.

FDA currently has OMB approval for the collection of information entitled ''Application for Food and Drug Administration Approval to Market a New Drug'' (OMB control number 0910–0001). This collection of information includes, among other things:

- The requirements in §§ 314.50(i) and 314.94(a)(12) for submission of an appropriate patent certification or statement in a 505(b)(2) application or ANDA;
- the requirements in §§ 314.52 and 314.95 for a 505(b)(2) or ANDA applicant to send notice of any paragraph IV certification to each patent owner and the NDA holder and to amend its 505(b)(2) application or ANDA to certify that notice has been provided and to document receipt of the notice;
- the content requirements in § 314.54 for a 505(b)(2) application;
- the requirements in §§ 314.60 and 314.96 for applicants that amend an unapproved 505(b)(2) application or ANDA, respectively;
- the requirements in §§ 314.70 and 314.97 for supplements submitted to FDA for certain changes to an approved 505(b)(2) application or ANDA;
- the requirements in §§ 314.90 and 314.99 for applicants that request waivers from FDA for compliance with §§ 314.50 through 314.81 or §§ 314.92 through 314.99, respectively;
- the procedures in § 314.107(c) by which a first applicant notifies FDA of the date of first commercial marketing;
- the requirement in § 314.107(e) for an applicant to submit to FDA a copy of certain court decisions related to a patent that is the subject of a paragraph IV certification;
- the requirement in § 314.107(f) for a 505(b)(2) or ANDA applicant to notify FDA immediately of the filing of any legal action within 45 days of receipt of the notice of paragraph IV certification by each patent owner or the NDA holder; and
- the requirement in § 314.107(f) for a patent owner or NDA holder who is an exclusive patent licensee that waives its opportunity to file a legal action for patent infringement within the 45-day period to submit to FDA a waiver in the specified format.

In addition, FDA has OMB approval for the collection of information entitled ''General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions'' (OMB control number 0910–0191). This collection of information includes, among other things, the requirements in § 314.93 for submitting a suitability petition in accordance with 21 CFR 10.20 and 10.30.

FDA also has OMB approval for the collection of information entitled ''Applications for Food and Drug Administration Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed'' (OMB control number 0910–0513). This collection of information includes the requirements in § 314.50(h) for submission of patent information in an NDA, an amendment, or a supplement, as described in § 314.53. Section 314.53 requires that an applicant submitting an NDA, an amendment, or a supplement, except as provided in § 314.53(d)(2), submit on Forms FDA 3542a and 3542 the required patent information described in this section.

Under section 505(b), (c), and (j) of the FD&C Act and this final rule, the following information must be submitted to FDA but is not currently approved by OMB under the PRA.

Section 314.50(i)(1)(i)(C) requires a 505(b)(2) applicant to submit an appropriate patent certification or statement for each patent listed in the Orange Book for one drug product approved in an NDA that is pharmaceutically equivalent to the proposed drug product for which the original 505(b)(2) application is submitted and was approved before the original 505(b)(2) application was submitted. Section 314.54 also describes this requirement. In general, 505(b)(2) applications submitted for a proposed drug product for which there is an approved pharmaceutical equivalent already cite the pharmaceutically equivalent product as a listed drug relied upon to support approval. However, based on our experience reviewing 505(b)(2) applications, we estimate that § 314.50(i)(1)(i)(C) may result in two instances per year in which an applicant is required to identify a pharmaceutically equivalent drug product as a listed drug relied upon and to comply with applicable regulatory requirements (including submission of an appropriate patent certification or statement for each patent listed in the Orange Book for a pharmaceutically equivalent drug product approved in an NDA). Based on an average of 3.4 patents submitted by an NDA holder for listing in the Orange Book, we calculate that the two instances in which a 505(b)(2) applicant is required to identify a pharmaceutically equivalent drug product as a listed drug relied upon will result in 6.8 patent certifications or statements per year. The burden associated with this requirement in § 314.50(i)(1)(i)(C) is approximately 2 hours per response. In addition, if the patent certification submitted pursuant to § 314.50(i)(1)(i)(C) is a paragraph IV certification, the applicant also must comply with the requirements in § 314.52 for notice of paragraph IV certification.

The burden estimate for sending notice of a paragraph IV certification reflects other changes that reduce the currently approved burden for § 314.52 from 16 hours per response to 15 hours per response, and the additional content requirement in § 314.52(c) that increases the estimated burden by 0.33 hours per response. We are providing an estimate of 15 respondents for § 314.52(a), (b), and (e) to reflect the additional burden that may arise from the requirement in § 314.50(i)(1)(i)(C) if the two 505(b)(2)

applicants submit paragraph IV certifications and to update data regarding the estimated number of 505(b)(2) applications that contain one or more paragraph IV certifications, which adds approximately 675 hours (15 hours per response) to the currently approved burden. We separately describe and estimate the burden of the additional content requirement in § 314.52(c).

Sections 314.52(a) and 314.95(a) expand the acceptable delivery methods that may be used to send notice of paragraph IV certification to the NDA holder and each patent owner, and thereby reduce the burden on applicants to submit, under existing § 314.52(a) and (e), a request to FDA to use common alternate delivery methods. We receive approximately 390 written inquiries per year from 505(b)(2) or ANDA applicants requesting permission to send notice of paragraph IV certification by an overnight delivery service. Sections 314.52(a) and 314.95(a) eliminate the requirement to submit a request to use a designated delivery service, as defined in §§ 314.52(g) and 314.95(g). We estimate that approximately 97.5 percent of these written inquiries will no longer be required because the alternate delivery method would fall within the definition of a ''designated delivery service'' in §§ 314.52(g) and 314.95(g).

Sections 314.50(i)(6) and 314.94(a)(12)(viii) require a 505(b)(2) or ANDA applicant to amend its patent certification from a paragraph IV certification to a paragraph III certification after the court enters a final decision from which no appeal has been or can be taken, or signs and enters a settlement order or consent decree with a finding of infringement (unless the patent also is found invalid). Sections 314.50(i)(6) and 314.94(a)(12)(viii) also require a 505(b)(2) or ANDA applicant to submit an amended patent certification in certain circumstances after the NDA holder has requested to remove a patent or patent information from the list.

Based on our experience receiving submissions of court decisions or orders with a finding of infringement, and instances in which the patent or patent information has been removed from the list at the request of the NDA holder, we estimate that this requirement may result in approximately 17 and 153 instances per year in which an applicant amends its 505(b)(2) application or ANDA, respectively, to submit a revised patent certification. The burden hours associated with this requirement will be approximately 2 hours per response.

Sections 314.50(i)(6)(iii)(A)(*2*) and 314.94(a)(12)(viii)(C)(*1*)(*ii*) expressly codify the current requirement for a 505(b)(2) or ANDA applicant to submit a patent certification or statement if, after submission of the application, a new patent is issued by the USPTO that in the opinion of the applicant and to the best of its knowledge, claims the listed drug or an approved use for such listed drug and for which information is required to be filed by the NDA holder.

Section 314.95(c) requires that the notice of paragraph IV certification contain a statement that the applicant has received the paragraph IV acknowledgment letter. In addition, § 314.52(c) requires that the notice of paragraph IV certification contain a statement that a 505(b)(2) application that contains any required bioavailability or bioequivalence data has been submitted by the applicant and filed by FDA, as required by section 505(b)(3)(D)(i) of the FD&C Act. We estimate that these additional content requirements for the notice of paragraph IV certification would increase the burden of providing notice of paragraph IV certification by approximately 20 minutes. Based on an estimated average of 20 505(b)(2) applications filed per year that contain one or more paragraph IV certifications (plus the additional burden that may arise from the requirement in § 314.50(i)(1)(i)(C) if the 2 505(b)(2) applicants submit paragraph IV certifications) and 400 ANDAs received per year that contain one or more paragraph IV certifications, we estimate that there will be 60 and 1,200 responses per year, respectively, and the burden hours associated with this requirement will be approximately 20 minutes per response.

Sections 314.52(d)(1) and 314.95(d)(1) require notice of paragraph IV certification regardless of whether notice has already been provided for another paragraph IV certification contained in the 505(b)(2) application or ANDA or an amendment or supplement to the 505(b)(2) application or ANDA, as required by section 505(b)(3)(B)(ii) and (j)(2)(B)(ii)(II) of the FD&C Act. Since enactment of the MMA in 2003, FDA has regulated directly from the statute and required notice of paragraph IV certification in these circumstances, and the burden associated with this statutory requirement is currently approved under OMB control number 0910–0001.

Sections 314.52(e) and 314.95(e) would permit a 505(b)(2) or ANDA applicant to submit a single amendment containing documentation of timely sending and receipt of notice of paragraph IV certification. Currently, an applicant is required to amend its 505(b)(2) application or ANDA both at the time of sending notice of paragraph IV certification and after the notice was received by each patent owner and the NDA holder (see existing §§ 314.52(b) and (e) and 314.95(b) and (e)). Section 314.95(e) also requires an ANDA applicant to include in its amendment a dated printout of the Orange Book entry for the RLD. The burden associated with this statutory requirement is currently approved under OMB control number 0910–0001.

Section 314.53(c)(2) decreases the patent information that NDA applicants are currently required to submit for listing in the Orange Book. Section 314.53(c)(2) requires submission of patent information on whether a drug substance patent claims a polymorph only if such patent claims only a polymorph that is the same active ingredient described in the NDA or supplement. Section 314.53(c)(2) also provides that an applicant that submits information for a patent that claims either the drug substance or drug product and meets the requirements for patent listing on that basis is not required to provide information on whether that patent also claims the drug product or drug substance, respectively. Section 314.53(c)(2) also modifies requirements for submission of patent information on method-of-use patents. The information collection resulting from existing § 314.50(h) (citing § 314.53) and Form FDA 3542a has been approved by OMB under control number 0910–0513 for FDA's estimate of 20 hours per response. We previously estimated that the burden of Form FDA 3542a would fall by 3 hours per response. We now estimate that the burden for Form FDA 3542a will be reduced by 5 hours from 20 hours to 15 hours per response; we further estimate that the burden for Form FDA 3542 will increase by 5 hours from 5 to 10 hours per response. We have shifted a portion of the time spent preparing Form FDA 3542a to the estimated time preparing Form FDA 3542 to reflect the additional time spent by the NDA holder to develop the use code in accordance with FDA's revised regulations and identify the specific section(s) and subsection(s) of labeling that describe the specific approved method of use claimed by the patent.

Section 314.53(d)(2) avoids duplicative submission of patent information that would accompany supplements to NDAs and requires such information only for a supplement to add or change the dosage form or route of administration, to add or change the strength, to change the drug product

from prescription to OTC use, or to revise previously submitted patent information that differently or no longer claims the changed product.

Section 314.53(f)(1) provides a more detailed description of the procedure for patent listing disputes directed to the accuracy or relevance of submitted patent information, and establishes additional requirements for patent listing disputes directed to method-of-use claims. Based on our experience, we estimate that there may be approximately 12 instances per year in which a person submits a patent listing dispute, and a corresponding 12 instances per year in which the NDA holder is required to respond to the patent listing dispute. In light of the additional requirements for patent listing disputes directed to method-of-use claims, we estimate that the burden associated with § 314.53(f)(1) will be approximately 10 hours per response.

Section 314.53(f)(2) expressly requires correction or change of patent information if the NDA holder determines that a patent or patent claim no longer meets the statutory requirements for listing, if the NDA holder is required by court order to amend patent information or withdraw a patent from the list, or if the term of a listed patent is extended under 35 U.S.C. 156(e). We estimate that these corrections and changes of patent information would result in approximately 39 submissions of Form FDA 3542 or other written submission, as provided in § 314.53(f)(2), by approximately 27 NDA holders. We further estimate that the burden hours associated with the requirement in § 314.53(f)(2) would be approximately 1 hour per response.

Section 505(b)(4)(A) and (j)(2)(D)(i) of the FD&C Act generally prohibits the submission of certain types of changes in an amendment or a supplement to a 505(b)(2) application or an ANDA, respectively. Sections 314.60(e) and 314.70(h) would prohibit an applicant from amending or supplementing a 505(b)(2) application to seek approval of a drug that has been modified to have a different active ingredient, different route of administration, different dosage form, or certain differences in excipients than the drug proposed in the original submission of the 505(b)(2) application. These changes must be requested in a new 505(b)(2) application. This final requirement conforms with FDA's current policy regarding the types of proposed changes to a drug product that should be submitted as a separate application (see guidance for industry on ''Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees'' (December 2004), available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*). Accordingly, the burden associated with this statutory requirement is currently approved under OMB control number 0910–0001.

Sections 314.60(f) and 314.96(d) require an applicant to submit a patent certification if approval is sought for the following types of amendments to a 505(b)(2) application or ANDA: (1) To add a new indication or other condition of use; (2) to add a new strength; (3) to make other than minor changes in product formulation; or (4) to change the physical form or crystalline structure of the active ingredient. Although currently the submission of a patent certification is required if, at any time before approval, the applicant learns that the previously submitted patent certification is no longer accurate with respect to the pending application or supplement, as amended, the patent certification requirements would be broadened under this regulation. We estimate that this broadened requirement may result in approximately six instances per year in which an applicant is required to submit a patent certification with an amendment to its 505(b)(2) application. We further estimate that this requirement may result in approximately 100 instances per year in which an applicant is required to submit a patent certification with an amendment to its ANDA. The burden hours associated with these requirements are estimated to be approximately 2 hours per response.

Sections 314.96(c) and 314.97(b) prohibit an ANDA applicant from amending or supplementing an ANDA to seek approval of a drug referring to a listed drug that is different from the RLD identified in the ANDA. An applicant must submit a change of the RLD in a new ANDA. We estimate that approximately one ANDA applicant per year will be required to submit a new ANDA instead of submitting an amendment for a change of the RLD. We also estimate that approximately one ANDA applicant per year will be required to submit a new ANDA instead of submitting a supplement for a change of the RLD. We further estimate that the burden of submitting an ANDA and complying with applicable regulatory requirements, including any required study to demonstrate bioequivalence to the new RLD, will be approximately 300 hours for each of the estimated two responses per year.

Section 314.107(e) expands the scope of the court actions and written consent to approval related to a patent described in § 314.107(b)(3) that are required to be submitted to FDA. Section 314.107(e) also requires submission of any court order pursuant to 35 U.S.C. 271(e)(4)(A) ordering that a 505(b)(2) application or ANDA may be approved no earlier than the date specified. Based on our experience, we estimate that 247 505(b)(2) and ANDA applicants will be required to submit a copy of a court action, written consent to approval, or written notification of appeal in approximately 494 instances per year. We continue to estimate that the burden associated with submitting a copy of these documents to FDA (as approved in OMB control number 0910–0001) is approximately 30 minutes per response.

The estimated burden of this collection of information is described in Table 3.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
314.50(i)(1)	2	3.4	6.8	2	14
314.50(i)(6)	17	1	17	2	34
314.52(a), (b), and (e)	15	3	45	15	675
314.52(c)	22	3	66	0.33 (20 minutes)	22
314.53(f)(1)	24	1	24	10	240
314.53(f)(2)	27	1.4	39	1	39
314.60(f)	6	1	6	2	12
314.94(a)(12)(viii)	153	1	153	2	306
314.95(c)	400	3	1,200	0.33 (20 minutes)	400

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
314.96(c)	1	1	1	300	300
314.96(d)	100	1	100	2	200
314.97(b)	1	1	1	300	300
314.107(e)	247	2	494	0.5 (30 minutes)	247
Total Reporting Burden Hours					2,789

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov*. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Federal Trade Commission, Report on ''Generic Drug Entry Prior to Patent Expiration: An FTC Study'' (July 2002), available at *http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf*.
2. Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Abbreviated New Drug Applications and 505(b)(2) Applications; Final Rule, available at *http://www.fda.gov/aboutfda/reportsmanualsforms/reports/economicanalyses/default.htm*.

List of Subjects

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 320

Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 314 and 320 are amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for part 314 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 355f, 356, 356a, 356b, 356c, 356e, 360cc, 371, 374, 379e, 379k–1.

■ 2. Section 314.3 is revised to read as follows:

§ 314.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to those terms when used in this part and part 320 of this chapter.

(b) The following definitions of terms apply to this part and part 320 of this chapter:

180-day exclusivity period is the 180-day period beginning on the date of the first commercial marketing of the drug (including the commercial marketing of the reference listed drug) by any first applicant. The 180-day period ends on the day before the date on which an ANDA submitted by an applicant other than a first applicant could be approved.

505(b)(2) application is an NDA submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for a drug for which at least some of the investigations described in section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act and relied upon by the applicant for approval of the NDA were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

Abbreviated application, abbreviated new drug application, or ANDA is the application described under § 314.94, including all amendments and supplements to the application.

Acknowledgment letter is a written, postmarked communication from FDA to an applicant stating that the Agency has determined that an ANDA is sufficiently complete to permit a substantive review. An acknowledgment letter indicates that the ANDA is regarded as received.

Act is the Federal Food, Drug, and Cosmetic Act (section 201 *et seq.* (21 U.S.C. 301 *et seq.*)).

Active ingredient is any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

Active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

ANDA holder is the applicant that owns an approved ANDA.

Applicant is any person who submits an NDA (including a 505(b)(2) application) or ANDA or an amendment or supplement to an NDA or ANDA under this part to obtain FDA approval of a new drug and any person who owns an approved NDA (including a 505(b)(2) application) or ANDA.

Application, new drug application, or NDA is the application described under § 314.50, including all amendments and supplements to the application. An NDA refers to ''stand-alone'' applications submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act and to 505(b)(2) applications.

Approval letter is a written communication to an applicant from FDA approving an NDA or an ANDA.

Assess the effects of the change is to evaluate the effects of a manufacturing change on the identity, strength, quality, purity, and potency of a drug product as these factors may relate to the safety or effectiveness of the drug product.

Authorized generic drug is a listed drug, as defined in this section, that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade with labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug.

Bioavailability is the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action.

Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (*e.g.,* in certain extended-release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action. This applies only if the difference in the rate at which the active ingredient or moiety becomes available at the site of drug action is intentional and is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. For drug products that are not intended to be absorbed into the bloodstream, bioequivalence may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action.

Bioequivalence requirement is a requirement imposed by FDA for in vitro and/or in vivo testing of specified drug products that must be satisfied as a condition of marketing.

Class 1 resubmission is the resubmission of an NDA or efficacy supplement, following receipt of a complete response letter, that contains one or more of the following: Final printed labeling, draft labeling, certain safety updates, stability updates to support provisional or final dating periods, commitments to perform postmarketing studies (including proposals for such studies), assay validation data, final release testing on the last lots used to support approval, minor reanalyses of previously submitted data, and other comparatively minor information.

Class 2 resubmission is the resubmission of an NDA or efficacy supplement, following receipt of a complete response letter, that includes any item not specified in the definition of ''Class 1 resubmission,'' including any item that would require presentation to an advisory committee.

Commercial marketing is the introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA, outside the control of the ANDA applicant, except that the term does not include transfer of the drug product for investigational use under part 312 of this chapter or transfer of the drug product to parties identified in the ANDA for reasons other than sale. Commercial marketing includes the introduction or delivery for introduction into interstate commerce of the reference listed drug by the ANDA applicant.

Complete response letter is a written communication to an applicant from FDA usually describing all of the deficiencies that the Agency has identified in an NDA or ANDA that must be satisfactorily addressed before it can be approved.

Component is any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

Date of approval is the date on the approval letter from FDA stating that the NDA or ANDA is approved, except that the date of approval for an NDA described in section 505(x)(1) of the Federal Food, Drug, and Cosmetic Act is determined as described in section 505(x)(2) of the Federal Food, Drug, and Cosmetic Act. ''Date of approval'' refers only to a final approval and not to a tentative approval.

Dosage form is the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product. This includes such factors as:

(1) The physical appearance of the drug product;

(2) The physical form of the drug product prior to dispensing to the patient;

(3) The way the product is administered; and

(4) The design features that affect frequency of dosing.

Drug product is a finished dosage form, *e.g.,* tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Drug substance is an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

Efficacy supplement is a supplement to an approved NDA proposing to make one or more related changes from among the following changes to product labeling:

(1) Add or modify an indication or claim;

(2) Revise the dose or dose regimen;

(3) Provide for a new route of administration;

(4) Make a comparative efficacy claim naming another drug product;

(5) Significantly alter the intended patient population;

(6) Change the marketing status from prescription to over-the-counter use;

(7) Provide for, or provide evidence of effectiveness necessary for, the traditional approval of a product originally approved under subpart H of this part; or

(8) Incorporate other information based on at least one adequate and well-controlled clinical study.

FDA or Agency is the Food and Drug Administration.

First applicant is an ANDA applicant that, on the first day on which a substantially complete application containing a paragraph IV certification is submitted for approval of a drug, submits a substantially complete application that contains, and for which the applicant lawfully maintains, a paragraph IV certification for the drug.

Inactive ingredient is any component other than an active ingredient.

Listed drug is a new drug product that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act for safety and effectiveness or under section 505(j) of the Federal Food, Drug, and Cosmetic Act, which has not been withdrawn or suspended under section 505(e)(1) through (5) or section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product's identification in the current edition of FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (the list) as an approved drug. A drug product is deemed to be a listed drug on the date of approval for the NDA or ANDA for that drug product.

NDA holder is the applicant that owns an approved NDA.

Newly acquired information is data, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (*e.g.,* meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

Original application or original NDA is a pending NDA for which FDA has never issued a complete response letter or approval letter, or an NDA that was submitted again after FDA had refused to file it or after it was withdrawn without being approved.

Paragraph IV acknowledgment letter is a written, postmarked communication from FDA to an applicant stating that the Agency has determined that a 505(b)(2) application or ANDA containing a paragraph IV certification is sufficiently complete to permit a substantive review. A paragraph IV acknowledgment letter indicates that the 505(b)(2) application is regarded as filed or the ANDA is regarded as received.

Paragraph IV certification is a patent certification of invalidity, unenforceability, or noninfringement described in § 314.50(i)(1)(i)(A)(*4*) or § 314.94(a)(12)(i)(A)(*4*).

Patent owner is the owner of the patent for which information is submitted for an NDA.

Pharmaceutical alternatives are drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form or as the same salt or ester. Each such drug product individually meets either the identical or its own respective compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates.

Pharmaceutical equivalents are drug products in identical dosage forms and route(s) of administration that contain identical amounts of the identical active drug ingredient, *i.e.,* the same salt or ester of the same therapeutic moiety, or, in the case of modified-release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates.

Postmark is an independently verifiable evidentiary record of the date on which a document is transmitted, in an unmodifiable format, to another party. For postmarks made by the U.S. Postal Service or a designated delivery service, the date of transmission is the date on which the document is received by the domestic mail service of the U.S. Postal Service or by a designated delivery service. For postmarks documenting an electronic event, the date of transmission is the date (in a particular time zone) that FDA sends the electronic transmission on its host system as evidenced by a verifiable record. If the sender and the intended recipient are located in different time zones, it is the sender's time zone that provides the controlling date of electronic transmission.

Reference listed drug is the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA.

Reference standard is the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an in vivo bioequivalence study required for approval.

Resubmission, in the context of a complete response letter, is submission by the applicant of all materials needed to fully address all deficiencies identified in the complete response letter. An NDA or ANDA for which FDA issued a complete response letter, but which was withdrawn before approval and later submitted again, is not a resubmission.

Right of reference or use is the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an NDA, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary.

Same drug product formulation is the formulation of the drug product submitted for approval and any formulations that have minor differences in composition or method of manufacture from the formulation submitted for approval, but are similar enough to be relevant to the Agency's determination of bioequivalence.

Specification is the quality standard (*i.e.,* tests, analytical procedures, and acceptance criteria) provided in an approved NDA or ANDA to confirm the quality of drug substances, drug products, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of a drug substance or drug product. For the purpose of this definition, acceptance criteria means numerical limits, ranges, or other criteria for the tests described.

Strength is the amount of drug substance contained in, delivered, or deliverable from a drug product, which includes:

(1)(i) The total quantity of drug substance in mass or units of activity in a dosage unit or container closure (*e.g.,* weight/unit dose, weight/volume or weight/weight in a container closure, or units/volume or units/weight in a container closure); and/or, as applicable.

(ii) The concentration of the drug substance in mass or units of activity per unit volume or mass (*e.g.,* weight/weight, weight/volume, or units/volume); or

(2) Such other criteria the Agency establishes for determining the amount of drug substance contained in, delivered, or deliverable from a drug product if the weights and measures described in paragraph (i) of this definition do not apply (*e.g.,* certain drug-device combination products for

which the amount of drug substance is emitted per use or unit time).

Substantially complete application is an ANDA that on its face is sufficiently complete to permit a substantive review. Sufficiently complete means that the ANDA contains all the information required under section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act and does not contain a deficiency described in § 314.101(d) and (e).

Tentative approval is notification that an NDA or ANDA otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved because there is a 7-year period of orphan exclusivity for a listed drug under section 527 of the Federal Food, Drug, and Cosmetic Act and § 316.31 of this chapter, or that a 505(b)(2) application or ANDA otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved until the conditions in § 314.107(b)(1)(iii), (b)(3), or (c) are met; because there is a period of exclusivity for the listed drug under § 314.108; because there is a period of pediatric exclusivity for the listed drug under section 505A of the Federal Food, Drug, and Cosmetic Act; because there is a period of exclusivity for the listed drug under section 505E of the Federal Food, Drug, and Cosmetic Act; or because a court order pursuant to 35 U.S.C. 271(e)(4)(A) orders that the NDA or ANDA may be approved no earlier than the date specified. A drug product that is granted tentative approval is not an approved drug and will not be approved until FDA issues an approval letter after any necessary additional review of the NDA or ANDA.

The list is the list of approved drug products published in FDA's current ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' available electronically on FDA's Web site at *http://www.fda.gov/cder*.

Therapeutic equivalents are approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

■ 3. Amend § 314.50 as follows:

■ a. Remove the word ''shall'' and add in its place the word ''must'' wherever it appears in paragraphs (a) introductory text, (a)(5), (d)(1)(v), (d)(5)(v), (d)(5)(vi)(*a*) and (*b*), (e)(2) introductory text, (f)(3), (g)(2), and (k);

■ b. Remove the word ''application'' and add in its place ''NDA'' wherever it appears in paragraphs (a)(5), (b), (c)(1), (c)(2)(i), (c)(2)(iv) through (viii), (d) introductory text, (d)(1)(i), (d)(1)(ii)(*a*), (d)(1)(iii) through (v), (d)(3)(ii), (d)(5)(iv), (d)(5)(vi)(*b*), (e)(1)(i) introductory text, (e)(2) introductory text, (f) introductory text, (f)(1) through (3), (g)(2), (h), (j)(4) introductory text, (j)(4)(i) and (ii), (k), (l) heading, (l)(1) introductory text, and (l)(4);

■ c. Remove the word ''act'' and add in its place ''Federal Food, Drug, and Cosmetic Act'' in paragraphs (d) introductory text, (d)(5)(vi)(*b*), and (j)(3);

■ d. Remove the phrase ''Prior to the submission of'' and add in its place the words ''Before submitting'' and remove the phrase ''are required to'' and add in its place the word ''must'' wherever it appears in paragraph (d)(5)(vi)(*b*);

■ e. Remove the word ''shall'' and add in its place the word ''must'' and remove the phrase ''new drug application'' and add in its place ''NDA'' in paragraph (j) introductory text; and

■ f. Revise the section heading, introductory text, and paragraphs (a)(1), (e)(1) introductory text, (f)(4), (g)(3), (i), the first two sentences of paragraph (j)(4)(iii), and (l)(2) and (3).

The revisions read as follows:

§ 314.50 Content and format of an NDA.

NDAs and supplements to approved NDAs are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. Three copies of the NDA are required: An archival copy, a review copy, and a field copy. An NDA for a new chemical entity will generally contain an application form, an index, a summary, five or six technical sections, case report tabulations of patient data, case report forms, drug samples, and labeling, including, if applicable, any Medication Guide required under part 208 of this chapter. Other NDAs will generally contain only some of those items, and information will be limited to that needed to support the particular submission. These include an NDA of the type described in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, an amendment, and a supplement. The NDA is required to contain reports of all investigations of the drug product sponsored by the applicant, and all other information about the drug pertinent to an evaluation of the NDA that is received or otherwise obtained by the applicant from any source. FDA will maintain guidance documents on the format and content of NDAs to assist applicants in their preparation.

(a) * * *

(1) The name and address of the applicant; the date of the NDA; the NDA number if previously issued (for example, if the NDA is a resubmission or an amendment or supplement); the name of the drug product, including its established, proprietary, code, and chemical names; the dosage form and strength; the route of administration; the identification numbers of all INDs (as defined in § 312.3(b) of this chapter) that are referenced in the NDA; the identification numbers of all drug master files and other applications under this part that are referenced in the NDA; and the drug product's proposed indications for use.

* * * * *

(e) * * * (1) Upon request from FDA, the applicant must submit the samples described below to the places identified in the Agency's request. FDA generally will ask applicants to submit samples directly to two or more Agency laboratories that will perform all necessary tests on the samples and validate the applicant's analytical procedures.

* * * * *

(f) * * *

(4) *Presentation and format.* Applicants are invited to meet with FDA before submitting an NDA to discuss the presentation and format of supporting information. If the applicant and FDA agree, the applicant may submit tabulations of patient data and case report forms in an alternate form.

(g) * * *

(3) If an applicant who submits an NDA under section 505(b) of the Federal Food, Drug, and Cosmetic Act obtains a ''right of reference or use,'' as defined under § 314.3(b), to an investigation described in clause (A) of section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, the applicant must include in its NDA a written statement signed by the owner of the data from each such investigation that the applicant may rely on in support of the approval of its NDA, and provide FDA access to, the underlying raw data that provide the basis for the report of the investigation submitted in its NDA.

* * * * *

(i) *Patent certification*—(1) *Contents.* A 505(b)(2) application is required to contain the following:

(i) *Patents claiming drug substance, drug product, or method of use.* (A) An appropriate patent certification or statement with respect to each patent issued by the U.S. Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims the drug substance or drug product on which investigations that are relied upon by the applicant for approval of its 505(b)(2) application

were conducted or that claims an approved use for such drug and for which information is required to be filed under section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53. For each such patent, the applicant must provide the patent number and certify, in its opinion and to the best of its knowledge, one of the following circumstances:

(*1*) That the patent information has not been submitted to FDA. The applicant must entitle such a certification ''Paragraph I Certification'';

(*2*) That the patent has expired. The applicant must entitle such a certification ''Paragraph II Certification'';

(*3*) The date on which the patent will expire. The applicant must entitle such a certification ''Paragraph III Certification''; or

(*4*)(*i*) That the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the 505(b)(2) application is submitted. The applicant must entitle such a certification ''Paragraph IV Certification''. This certification must be submitted in the following form:

I, (*name of applicant*), certify that Patent No. ____ (*is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of*) (*name of proposed drug product*) for which this 505(b)(2) application is submitted.

(*ii*) The certification must be accompanied by a statement that the applicant will comply with the requirements under § 314.52(a) with respect to providing a notice to each owner of the patent or its representative and to the NDA holder (or, if the NDA holder does not reside or maintain a place of business within the United States, its attorney, agent, or other authorized official) for the drug product that is claimed by the patent or a use of which is claimed by the patent and with the requirements under § 314.52(b) with respect to sending the notice and under § 314.52(c) with respect to the content of the notice.

(B) If the drug on which investigations that are relied upon by the applicant were conducted is itself a licensed generic drug of a patented drug first approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act, an appropriate patent certification or statement under this section with respect to each patent that claims the first-approved patented drug or that claims an approved use for such a drug.

(C) If, before the date of submission of an original 505(b)(2) application, there is a drug product approved in an NDA that is pharmaceutically equivalent to the drug product for which the original 505(b)(2) application is submitted, an appropriate patent certification or statement under this section with respect to each patent that claims the drug substance or drug product or that claims an approved use for one such drug product.

(ii) *No relevant patents.* If, in the opinion of the applicant and to the best of its knowledge, there are no patents described in paragraph (i)(1)(i) of this section, a certification in the following form:

In the opinion and to the best knowledge of (*name of applicant*), there are no patents that claim the drug or drugs on which investigations that are relied upon in this 505(b)(2) application were conducted or that claim a use of such drug or drugs.

(iii) *Method-of-use patent.* (A) If information that is submitted under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53 is for a method-of-use patent, and the labeling for the drug product for which the applicant is seeking approval does not include an indication or other condition of use that is covered by the method-of-use patent, a statement explaining that the method-of-use patent does not claim a proposed indication or other condition of use.

(B) If the labeling of the drug product for which the applicant is seeking approval includes an indication or other condition of use that, according to the patent information submitted under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53 or in the opinion of the applicant, is claimed by a method-of-use patent, the applicant must submit an applicable certification under paragraph (i)(1)(i) of this section.

(2) [Reserved]

(3) *Licensing agreements.* If a 505(b)(2) application is submitted for a drug or method of using a drug claimed by a patent and the applicant has a licensing agreement with the patent owner, the applicant must submit a paragraph IV certification as to that patent and a statement that the applicant has been granted a patent license. If the patent owner consents to approval of the 505(b)(2) application (if otherwise eligible for approval) as of a specific date, the 505(b)(2) application must contain a written statement from the patent owner that it has a licensing agreement with the applicant and that it consents to approval of the 505(b)(2) application as of a specific date.

(4) *Untimely filing of patent information.* (i) If a patent described in paragraph (i)(1)(i)(A) of this section is issued and the holder of the approved NDA for the patented drug does not file with FDA the required information on the patent within 30 days of issuance of the patent, an applicant who submitted a 505(b)(2) application that, before the submission of the patent information, contained an appropriate patent certification or statement is not required to submit a patent certification or statement to address the patent or patent information that is late-listed with respect to the pending 505(b)(2) application. Except as provided in § 314.53(f)(1), an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent will be considered untimely filing of patent information unless:

(A) The amendment to the description of the approved method(s) of use claimed by the patent is submitted within 30 days of patent issuance;

(B) The amendment to the description of the approved method(s) of use claimed by the patent is submitted within 30 days of approval of a corresponding change to product labeling; or

(C) The amendment to the description of the approved method(s) of use claimed by the patent is submitted within 30 days of a decision by the U.S. Patent and Trademark Office or by a Federal district court, the Court of Appeals for the Federal Circuit, or the U.S. Supreme Court that is specific to the patent and alters the construction of a method-of-use claim(s) of the patent, and the amendment contains a copy of the decision.

(ii) An applicant whose 505(b)(2) application is submitted after the NDA holder's untimely filing of patent information or whose 505(b)(2) application was previously filed but did not contain an appropriate patent certification or statement at the time of the patent submission must submit a certification under paragraph (i)(1)(i) of this section and/or a statement under paragraph (i)(1)(iii) of this section as to that patent.

(5) *Disputed patent information.* If an applicant disputes the accuracy or relevance of patent information submitted to FDA, the applicant may seek a confirmation of the correctness of the patent information in accordance with the procedures under § 314.53(f). Unless the patent information is withdrawn, the applicant must submit an appropriate certification or statement for each listed patent.

(6) *Amended certifications.* A patent certification or statement submitted under paragraphs (i)(1)(i) through (iii) of this section may be amended at any time before the approval of the 505(b)(2) application. An applicant must submit

an amended certification as an amendment to a pending 505(b)(2) application. If an applicant with a pending 505(b)(2) application voluntarily makes a patent certification for an untimely filed patent, the applicant may withdraw the patent certification for the untimely filed patent. Once an amendment is submitted to change the certification, the 505(b)(2) application will no longer be considered to contain the prior certification.

(i) *After finding of infringement.* An applicant who has submitted a paragraph IV certification and is sued for patent infringement must submit an amendment to change its certification if a court enters a final decision from which no appeal has been or can be taken, or signs and enters a settlement order or consent decree in the action that includes a finding that the patent is infringed, unless the final decision, settlement order, or consent decree also finds the patent to be invalid. In its amendment, the applicant must certify under paragraph (i)(1)(i)(A)(*3*) of this section that the patent will expire on a specific date or, with respect to a patent claiming a method of use, the applicant may instead provide a statement under paragraph (i)(1)(iii) of this section if the applicant amends its 505(b)(2) application such that the applicant is no longer seeking approval for a method of use claimed by the patent. Once an amendment for the change has been submitted, the 505(b)(2) application will no longer be considered to contain a paragraph IV certification to the patent. If a final decision finds the patent to be invalid and infringed, an amended certification is not required.

(ii) *After request to remove a patent or patent information from the list.* If the list reflects that an NDA holder has requested that a patent or patent information be removed from the list and no ANDA applicant is eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent or patent information will be removed and any applicant with a pending 505(b)(2) application (including a tentatively approved 505(b)(2) application) who has made a certification with respect to such patent must submit an amendment to withdraw its certification. In the amendment, the applicant must state the reason for withdrawing the certification or statement (that the patent has been removed from the list). If the list reflects that an NDA holder has requested that a patent or patent information be removed from the list and one or more first applicants are eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent will remain listed until any 180-day exclusivity based on that patent has expired or has been extinguished. A 505(b)(2) applicant is not required to provide or maintain a certification to a patent or patent information that remains listed only for purposes of a first applicant's 180-day exclusivity for its ANDA. Once an amendment to withdraw the certification has been submitted, the 505(b)(2) application will no longer be considered to contain a paragraph IV certification to the patent. If removal of a patent from the list results in there being no patents listed for the listed drug(s) identified in the 505(b)(2) application, the applicant must submit an amended certification reflecting that there are no listed patents.

(iii) *Other amendments.* (A) Except as provided in paragraphs (i)(4) and (i)(6)(iii)(B) of this section:

(*1*) An applicant must amend a submitted certification or statement if, at any time before the approval of the 505(b)(2) application, the applicant learns that the submitted certification or statement is no longer accurate; and

(*2*) An applicant must submit an appropriate patent certification or statement under paragraph (i)(1) of this section if, after submission of the 505(b)(2) application, a new patent is issued by the U.S. Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims a listed drug relied upon or that claims an approved use for such listed drug for which information is required to be filed under section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53.

(B) An applicant is not required to submit a supplement to change a submitted certification when information on an otherwise applicable patent is submitted after the approval of the 505(b)(2) application.

(j) * * *

(4) * * *

(iii) * * * If the applicant was the sponsor named in the Form FDA 1571 for an IND under which the new clinical investigation(s) that is essential to the approval of its NDA was conducted, identification of the IND by number. If the applicant was not the sponsor of the IND under which the clinical investigation(s) was conducted, a certification that the applicant or its predecessor in interest provided substantial support for the clinical investigation(s) that is essential to the approval of its NDA, and information supporting the certification. * * *

* * * * *

(l) * * *

(2) *Review copy.* The applicant must submit a review copy of the NDA. Each of the technical sections, described in paragraphs (d)(1) through (6) of this section, in the review copy is required to be separately bound with a copy of the application form required under paragraph (a) of this section and a copy of the summary required under paragraph (c) of this section.

(3) *Field copy.* The applicant must submit a field copy of the NDA that contains the technical section described in paragraph (d)(1) of this section, a copy of the application form required under paragraph (a) of this section, a copy of the summary required under paragraph (c) of this section, and a certification that the field copy is a true copy of the technical section described in paragraph (d)(1) of this section contained in the archival and review copies of the NDA.

* * * * *

■ 4. Section 314.52 is revised to read as follows:

§ 314.52 Notice of certification of invalidity, unenforceability, or noninfringement of a patent.

(a) *Notice of certification.* For each patent that claims the listed drug or drugs relied upon or that claims a use for such listed drug or drugs and for which the 505(b)(2) applicant submits a paragraph IV certification, the applicant must send notice of such certification by registered or certified mail, return receipt requested, or by a designated delivery service, as defined in paragraph (g) of this section, to each of the following persons:

(1) Each owner of the patent that is the subject of the certification or the representative designated by the owner to receive the notice. The name and address of the patent owner or its representative may be obtained from the U.S. Patent and Trademark Office; and

(2) The holder of the approved NDA under section 505(b) of the Federal Food, Drug, and Cosmetic Act for each drug product which is claimed by the patent or a use of which is claimed by the patent and for which the applicant is seeking approval, or, if the NDA holder does not reside or maintain a place of business within the United States, the NDA holder's attorney, agent, or other authorized official. The name and address of the NDA holder or its attorney, agent, or authorized official may be obtained by sending a written or electronic communication to the Orange Book Staff, Office of Generic Drugs, 7620 Standish Pl., Rockville, MD 20855, or to the Orange Book Staff at the email

address listed on the Agency's Web site at *http://www.fda.gov.*

(3) This paragraph (a) does not apply to a method-of-use patent that does not claim a use for which the applicant is seeking approval.

(4) An applicant may send notice by an alternative method only if FDA has agreed in advance that the method will produce an acceptable form of documentation.

(b) *Sending the notice.* (1) Except as provided under paragraph (d) of this section, the applicant must send the notice required by paragraph (a) of this section on or after the date of filing described in § 314.101(a)(2) or (3), as applicable, but not later than 20 days after the date of the postmark on the paragraph IV acknowledgment letter. The 20-day clock described in this paragraph (b) begins on the day after the date of the postmark on the paragraph IV acknowledgment letter. When the 20th day falls on Saturday, Sunday, or a Federal holiday, the 20th day will be the next day that is not a Saturday, Sunday, or Federal holiday.

(2) Any notice required by paragraph (a) of this section is invalid if it is sent before the date of filing described in § 314.101(a)(2) or, if FDA notifies the applicant that FDA has refused to file the 505(b)(2) application, before the date described in § 314.101(a)(3) on which the 505(b)(2) application is filed. The applicant will not have complied with this paragraph (b) until it sends valid notice.

(3) The applicant must submit to FDA an amendment to its 505(b)(2) application that includes a statement certifying that the notice has been provided to each person identified under paragraph (a) of this section and that the notice met the content requirement under paragraph (c) of this section. A copy of the notice itself need not be submitted to the Agency.

(c) *Content of a notice.* In the notice, the applicant must cite section 505(b)(3)(D) of the Federal Food, Drug, and Cosmetic Act and the notice must include, but is not limited to, the following information:

(1) A statement that a 505(b)(2) application that contains any required bioavailability or bioequivalence studies has been submitted by the applicant and filed by FDA.

(2) The NDA number.

(3) The established name, if any, as defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act, of the proposed drug product.

(4) The active ingredient, strength, and dosage form of the proposed drug product.

(5) The patent number and expiration date of each patent on the list alleged to be invalid, unenforceable, or not infringed.

(6) A detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed. The applicant must include in the detailed statement:

(i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed.

(ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.

(7) If the applicant alleges that the patent will not be infringed and the applicant seeks to preserve the option to later file a civil action for declaratory judgment in accordance with section 505(c)(3)(D) of the Federal Food, Drug, and Cosmetic Act, then the notice must be accompanied by an offer of confidential access to the 505(b)(2) application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the paragraph IV certification.

(8) If the applicant does not reside or have a place of business in the United States, the name and address of an agent in the United States authorized to accept service of process for the applicant.

(d) *Amendment or supplement to a 505(b)(2) application.* (1) If, after the date of filing described in § 314.101(a)(2) or (3), as applicable, an applicant submits an amendment or supplement to its 505(b)(2) application that includes a paragraph IV certification, the applicant must send the notice required by paragraph (a) of this section at the same time that the amendment or supplement to the 505(b)(2) application is submitted to FDA, regardless of whether the applicant has already given notice with respect to another such certification contained in the 505(b)(2) application or in an amendment or supplement to the 505(b)(2) application.

(2) If, before the date of filing described in § 314.101(a)(2) or (3), as applicable, an applicant submits a paragraph IV certification in an amendment, the applicant must send the notice required by paragraph (a) of this section in accordance with the procedures in paragraph (b) of this section.

(3) An applicant that submits an amendment or supplement to seek approval of a different strength must provide notice of any paragraph IV certification in accordance with paragraph (d)(1) or (2) of this section, as applicable.

(e) *Documentation of timely sending and receipt of notice.* The applicant must amend its 505(b)(2) application to provide documentation of the date of receipt of the notice required under paragraph (a) of this section by each person provided the notice. The amendment must be submitted to FDA within 30 days after the last date on which notice was received by a person described in paragraph (a) of this section. The applicant's amendment also must include documentation that its notice was sent on a date that complies with the timeframe required by paragraph (b) or (d) of this section, as applicable. FDA will accept, as adequate documentation of the date the notice was sent, a copy of the registered mail receipt, certified mail receipt, or receipt from a designated delivery service, as defined in paragraph (g) of this section. FDA will accept as adequate documentation of the date of receipt a return receipt, a signature proof of delivery by a designated delivery service, or a letter acknowledging receipt by the person provided the notice. An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance. A copy of the notice itself need not be submitted to the Agency.

(f) *Forty-five day period after receipt of notice.* If the requirements of this section are met, the Agency will presume the notice to be complete and sufficient and will count the day following the date of receipt of the notice by the patent owner or its representative and by the approved NDA holder or its attorney, agent, or other authorized official as the first day of the 45-day period provided for in section 505(c)(3)(C) of the Federal Food, Drug, and Cosmetic Act. FDA may, if the applicant amends its 505(b)(2) application with a written statement that a later date should be used, count from such later date.

(g) *Designated delivery services.* (1) For purposes of this section, the term ''designated delivery service'' is any delivery service provided by a trade or business that the Agency determines:

(i) Is available to the general public throughout the United States;

(ii) Records electronically to its database, kept in the regular course of its business, or marks on the cover in which any item referred to in this section is to be delivered, the date on which such item was given to such trade or business for delivery; and

(iii) Provides overnight or 2-day delivery service throughout the United States.

(2) FDA may periodically issue guidance regarding designated delivery services.

■ 5. Section 314.53 is revised to read as follows:

§ 314.53 Submission of patent information.

(a) *Who must submit patent information.* This section applies to any applicant who submits to FDA an NDA or an amendment to it under section 505(b) of the Federal Food, Drug, and Cosmetic Act and § 314.50 or a supplement to an approved NDA under § 314.70, except as provided in paragraph (d)(2) of this section.

(b) *Patents for which information must be submitted and patents for which information must not be submitted*—(1) *General requirements.* An applicant described in paragraph (a) of this section must submit to its NDA the required information, on the required FDA declaration form, set forth in paragraph (c) of this section for each patent that claims the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents. For patents that claim the drug substance, the applicant must submit information only on those patents that claim the drug substance that is the subject of the pending or approved NDA or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending NDA. For patents that claim only a polymorph that is the same as the active ingredient described in the approved or pending NDA, the applicant must certify in the required FDA declaration form that the applicant has test data, as set forth in paragraph (b)(2) of this section, demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA. For patents that claim a drug product, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA. For patents that claim a method of use, the applicant must submit information only on those patents that claim indications or other conditions of use for which approval is sought or has been granted in the NDA. The applicant must separately identify each pending or approved method of use and related patent claim(s). For approved NDAs, the NDA holder's description of the patented method of use required by paragraph (c)(2)(ii)(P)(*3*) of this section must describe only the approved method(s) of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. If the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, the applicant must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For approved NDAs, the NDA holder submitting information on the method-of-use patent must identify with specificity the section(s) and subsection(s) of the approved labeling that describes the method(s) of use claimed by the patent submitted. Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA.

(2) *Test data for submission of patent information for patents that claim only a polymorph.* The test data, referenced in paragraph (b)(1) of this section, must include the following:

(i) A full description of the polymorphic form of the drug substance, including its physical and chemical characteristics and stability; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and such specifications and analytical methods as are necessary to assure the identity, strength, quality, and purity of the polymorphic form of the drug substance;

(ii) The executed batch record for a drug product containing the polymorphic form of the drug substance and documentation that the batch was manufactured under current good manufacturing practice requirements;

(iii) Demonstration of bioequivalence between the executed batch of the drug product that contains the polymorphic form of the drug substance and the drug product as described in the NDA;

(iv) A list of all components used in the manufacture of the drug product containing the polymorphic form and a statement of the composition of the drug product; a statement of the specifications and analytical methods for each component; a description of the manufacturing and packaging procedures and in-process controls for the drug product; such specifications and analytical methods as are necessary to assure the identity, strength, quality, purity, and bioavailability of the drug product, including release and stability data complying with the approved product specifications to demonstrate pharmaceutical equivalence and comparable product stability; and

(v) Comparative in vitro dissolution testing on 12 dosage units each of the executed test batch and the NDA product.

(c) *Reporting requirements*—(1) *General requirements.* An applicant described in paragraph (a) of this section must submit the required patent information described in paragraph (c)(2) of this section for each patent that meets the requirements described in paragraph (b) of this section. We will not accept the patent information unless it is submitted on the appropriate form, Form FDA 3542 or 3542a, and contains the information required in paragraph (c)(2) of this section. These forms may be obtained on the Internet at *http://www.fda.gov* by searching for ''forms''.

(2) *Drug substance (active ingredient), drug product (formulation or composition), and method-of-use patents*—(i) *Original declaration.* For each patent that claims a drug substance (active ingredient), drug product (formulation and composition), or method of use, the applicant must submit Form FDA 3542a. The following information and verification is required, subject to the exceptions listed in paragraph (c)(2)(i)(S) of this section:

(A) NDA number;

(B) The NDA applicant's name, full address, phone number and, if available, fax number and email address;

(C) Trade name (or proposed trade name) of new drug;

(D) Active ingredient(s) of new drug;

(E) Strength(s) of new drug;

(F) Dosage form(s) and route(s) of administration of new drug, and whether the applicant proposes to market the new drug for prescription use or over-the-counter use;

(G) U.S. patent number, issue date, and expiration date of patent submitted;

(H) The patent owner's name, full address, phone number and, if available, fax number and email address;

(I) The name, full address, phone number and, if available, fax number and email address of an agent or representative who resides or maintains a place of business within the United

States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and §§ 314.52 and 314.95 (if patent owner or NDA applicant or holder does not reside or have a place of business within the United States);

(J) Information on whether the patent has been submitted previously for the NDA or supplement;

(K) If the patent has been submitted previously for listing, identify all change(s) from the previously submitted patent information and specify whether the change is related to the patent or related to an FDA action or procedure;

(L) Information on whether the patent is a product-by-process patent in which the product claimed is novel;

(M) Information on the drug substance (active ingredient) patent, including the following:

(*1*) Whether the patent claims a drug substance that is an active ingredient in the drug product described in the NDA or supplement;

(*2*) Whether the patent claims only a polymorph that is the same active ingredient that is described in the pending NDA or supplement;

(*3*) Whether the applicant has test data, described in paragraph (b)(2) of this section, demonstrating that a drug product containing only the polymorph will perform the same as the drug product described in the NDA or supplement, and a description of the polymorphic form(s) claimed by the patent for which such test data exist;

(*4*) Whether the patent claims only a metabolite of the active ingredient; and

(*5*) Whether the patent claims only an intermediate;

(N) Information on the drug product (composition/formulation) patent, including the following:

(*1*) Whether the patent claims the drug product for which approval is being sought, as defined in § 314.3; and

(*2*) Whether the patent claims only an intermediate;

(O) Information on each method-of-use patent, including the following:

(*1*) Whether the patent claims one or more methods of using the drug product for which approval is being sought and a description of each pending method of use and related patent claim of the patent being submitted;

(*2*) Identification of the specific section(s) and subsection(s) of the proposed labeling for the drug product that describes the method of use claimed by the patent submitted; and

(*3*) An applicant that submits information for a patent that claims one or more methods of using the drug product must also submit information described in either paragraph (c)(2)(i)(M) or (N) of this section, regarding whether that patent also claims either the drug substance (active ingredient) or the drug product (composition/formulation).

(P) Whether there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition), or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product;

(Q) A signed verification that states:

The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.

(R) Information on whether the applicant, patent owner or attorney, agent, representative, or other authorized official signed the form; the name of the person; and the full address, phone number and, if available, the fax number and email address; and

(S) Exceptions to required submission of patent information:

(*1*) If an applicant submits the information described in paragraph (c)(2)(i)(M) of this section for a patent that claims the drug substance (active ingredient) and meets the requirements for listing on that basis, then the applicant is not required to provide the information described in paragraph (c)(2)(i)(N) of this section on whether that patent also claims the drug product (composition/formulation);

(*2*) If an applicant submits the information described in paragraph (c)(2)(i)(N) of this section for a patent that claims the drug product (composition/formulation) and meets the requirements for listing on that basis, then the applicant is not required to provide the information described in paragraph (c)(2)(i)(M) of this section on whether that patent also claims the drug substance (active ingredient);

(*3*) If the applicant submits a supplement for a change other than one of the changes listed under paragraph (d)(2)(i) of this section, then the patent information submission requirements of paragraph (d)(2)(ii) of this section apply.

(ii) *Submission of patent information upon and after approval.* Within 30 days after the date of approval of its NDA or supplement, the applicant must submit Form FDA 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use. FDA will not list or publish patent information if it is not provided on this form or if the patent declaration does not contain the required information or indicates the patent is not eligible for listing. Patent information must also be submitted for patents issued after the date of approval of the NDA as required in paragraph (c)(2)(ii) of this section. As described in paragraph (d)(3) of this section, to be timely filed, patent information for patents issued after the date of approval of the NDA must be submitted to FDA within 30 days of the date of issuance of the patent. If the applicant submits the required patent information within the 30 days, but we notify an applicant that a declaration form is incomplete or shows that the patent is not eligible for listing, the applicant must submit an acceptable declaration form within 15 days of FDA notification to be considered timely filed. The following information and verification statement is required, subject to the exceptions listed in paragraph (c)(2)(ii)(T) of this section:

(A) NDA number;

(B) The NDA holder's name, full address, phone number and, if available, fax number and email address;

(C) Trade name of new drug;

(D) Active ingredient(s) of new drug;

(E) Strength(s) of new drug;

(F) Dosage form(s) and route(s) of administration of new drug, and whether the new drug is approved for prescription use or over-the-counter use;

(G) Approval date of NDA or supplement;

(H) U.S. patent number, issue date, and expiration date of patent submitted;

(I) The patent owner's name, full address, phone number and, if available, fax number and email address;

(J) The name, full address, phone number and, if available, fax number and email address of an agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and §§ 314.52 and 314.95 (if patent owner or NDA applicant or holder does not reside or have a place of business within the United States);

(K) Information on whether the patent has been submitted previously for the NDA or supplement;

(L) If the patent has been submitted previously for listing, identify all change(s) from the previously submitted patent information and specify whether the change is related to the patent or related to an FDA action or procedure;

(M) Information on whether the patent is a product-by-process patent in which the product claimed is novel;

(N) Information on the drug substance (active ingredient) patent, including the following:

(*1*) Whether the patent claims a drug substance that is an active ingredient in the drug product described in the approved NDA;

(*2*) Whether the patent claims only a polymorph that is the same as the active ingredient that is described in the approved NDA;

(*3*) Whether the applicant has test data, described in paragraph (b)(2) of this section, demonstrating that a drug product containing only the polymorph will perform the same as the drug product described in the approved NDA and a description of the polymorphic form(s) claimed by the patent for which such test data exist;

(*4*) Whether the patent claims only a metabolite of the active ingredient; and

(*5*) Whether the patent claims only an intermediate;

(O) Information on the drug product (composition/formulation) patent, including the following:

(*1*) Whether the patent claims the approved drug product as defined in § 314.3; and

(*2*) Whether the patent claims only an intermediate;

(P) Information on each method-of-use patent, including the following:

(*1*) Whether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use and related patent claim of the patent being submitted;

(*2*) Identification of the specific section(s) and subsection(s) of the approved labeling for the drug product that describes the method of use claimed by the patent submitted;

(*3*) The description of the patented method of use as required for publication, which must contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval (for example, if the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, then the applicant must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product); and

(*4*) An applicant that submits information for a patent that claims one or more methods of using the drug product must also submit information described in either paragraph (c)(2)(ii)(N) or (O) of this section, regarding whether that patent also claims either the drug substance (active ingredient) or the drug product (composition/formulation).

(Q) Whether there are no relevant patents that claim the approved drug substance (active ingredient), the approved drug product (formulation or composition), or approved method(s) of use and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product;

(R) A signed verification that states:

The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information or response to a request under 21 CFR 314.53(f)(1) is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.

(S) Information on whether the applicant, patent owner or attorney, agent, representative, or other authorized official signed the form; the name of the person; and the full address, phone number and, if available, the fax number and email address; and

(T) Exceptions to required submission of patent information:

(*1*) If an applicant submits the information described in paragraph (c)(2)(ii)(N) of this section for a patent that claims the drug substance (active ingredient) and meets the requirements for listing on that basis, then the applicant is not required to provide the information described in paragraph (c)(2)(ii)(O) of this section on whether that patent also claims the drug product (composition/formulation).

(*2*) If an applicant submits the information described in paragraph (c)(2)(ii)(O) of this section for a patent that claims the drug product (composition/formulation) and meets the requirements for listing on that basis, then the applicant is not required to provide the information described in paragraph (c)(2)(ii)(N) of this section on whether that patent also claims the drug substance (active ingredient).

(*3*) If the applicant submits a supplement for a change other than one of the changes listed under paragraph (d)(2)(i) of this section, then the patent information submission requirements of paragraph (d)(2)(ii) of this section apply.

(3) *No relevant patents.* If the applicant believes that there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition), or the method(s) of use for which the applicant has received approval, and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product, the applicant will verify this information in the appropriate form, Form FDA 3542 or 3542a.

(4) *Authorized signature.* The declarations required by this section must be signed by the applicant or patent owner, or the applicant's or patent owner's attorney, agent (representative), or other authorized official.

(d) *When and where to submit patent information*—(1) *Original NDA.* An applicant must submit with its original NDA submitted under this part, the information described in paragraph (c) of this section on each drug substance (active ingredient), drug product (formulation and composition), and method-of-use patent issued before the NDA is filed with FDA and for which patent information is required to be submitted under this section. If a patent is issued after the NDA is filed with FDA but before the NDA is approved, the applicant must, within 30 days of the date of issuance of the patent, submit the required patent information in an amendment to the NDA under § 314.60.

(2) *Supplements.* (i) An applicant must submit patent information required under paragraph (c) of this section for a patent that claims the drug substance, drug product, or method of use for which approval is sought in any of the following supplements:

(A) To add or change the dosage form or route of administration;

(B) To add or change the strength; or

(C) To change the drug product from prescription use to over-the-counter use.

(ii) If the applicant submits a supplement for a change other than one of the changes listed under paragraph (d)(2)(i) of this section (for example, to change the formulation, to add a new

indication or other condition of use, or to make any other patented change regarding the drug substance, drug product, or any method of use), the following patent information submission requirements apply:

(A) If existing patents for which information required by paragraph (c) of this section has already been submitted to FDA for the product approved in the original NDA claim the changed product, the applicant is not required to resubmit this patent information pursuant to paragraph (c) of this section unless the published description of the patented method of use would change upon approval of the supplement, and FDA will continue to list this patent information for the product;

(B) If one or more existing patents for which information has already been submitted to FDA no longer claim the changed product, the applicant must submit a request under paragraph (f)(2)(iv) of this section to remove that patent information from the list at the time of approval of the supplement;

(C) If one or more existing drug substance (active ingredient), drug product (formulation and composition), or method-of-use patents claim the changed product for which approval is sought in the supplement and such patent information has not been submitted to FDA, the applicant must submit the patent information required under paragraph (c) of this section.

(3) *Newly issued patents.* If a patent is issued for a drug substance, drug product, or method of use after an NDA is approved, the applicant must submit to FDA, as described in paragraph (d)(4) of this section, the required patent information within 30 days of the date of issuance of the patent. If the required patent information is not submitted within 30 days of the issuance of the patent, FDA will list the patent, but patent certifications or statements will be governed by the provisions regarding untimely filed patent information at §§ 314.50(i)(4) and (6) and 314.94(a)(12)(vi) and (viii).

(4) *Submission of Forms FDA 3542a and 3542*—(i) *Patent information submitted with the filing of an NDA, amendment, or supplement.* The applicant must submit patent information required by paragraphs (c)(1) and (c)(2)(i) of this section and § 314.50(h) or § 314.70(f) on Form FDA 3542a to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266, or to FDA in an electronic format submission that complies with § 314.50(l)(5). Form FDA 3542a should not be submitted to the Orange Book Staff in the Office of Generic Drugs.

(ii) *Patent information submitted upon and after approval of an NDA or supplement.* The applicant must submit patent information required by paragraphs (c)(1) and (c)(2)(ii) of this section on Form FDA 3542 to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266, or to FDA in an electronic format submission that complies with § 314.50(l)(5). Form FDA 3542 should not be submitted to the Orange Book Staff in the Office of Generic Drugs.

(5) *Submission date.* Patent information will be considered to be submitted to FDA for purposes of paragraph (d)(3) of this section as of the earlier of the date the information submitted on Form FDA 3542 is date-stamped by the Central Document Room, or officially received by FDA in an electronic format submission that complies with § 314.50(l)(5).

(6) *Identification.* Each submission of patent information, except information submitted with an original NDA, must bear prominent identification as to its contents, *i.e.,* ''Patent Information,'' or, if submitted after approval of an NDA, ''Time Sensitive Patent Information.''

(e) *Public disclosure of patent information.* FDA will publish in the list the patent number and expiration date of each patent that is required to be, and is, submitted to FDA by an applicant, and for each method-of-use patent, the description of the method of use claimed by the patent as required by § 314.53(c)(2)(ii)(P)(*3*). FDA will publish such patent information upon approval of the NDA, or, if the patent information is submitted by the applicant after approval of an NDA as provided under paragraph (d)(2) of this section, as soon as possible after the submission to the Agency of the patent information. A request for copies of the submitted patent information must be sent in writing to the Freedom of Information Staff at the address listed on the Agency's Web site at *http://www.fda.gov*. The submitted patent information, and requests to remove a patent or patent information from the list, may be subject to public disclosure.

(f) *Correction of patent information errors*—(1) *Requests by persons other than the NDA holder.* If any person disputes the accuracy or relevance of patent information submitted to the Agency under this section and published by FDA in the list, or believes that an NDA holder has failed to submit required patent information, that person must first notify the Agency in a written or electronic communication titled ''314.53(f) Patent Listing Dispute.'' The patent listing dispute communication must include a statement of dispute that describes the specific grounds for disagreement regarding the accuracy or relevance of patent information for FDA to send to the applicable NDA holder. For a dispute regarding the accuracy or relevance of patent information regarding an approved method of using the drug product, this statement of dispute must be only a narrative description (no more than 250 words) of the person's interpretation of the scope of the patent. This statement of dispute must only contain information for which the person consents to disclosure because FDA will send the text of the statement to the applicable NDA holder without review or redaction. The patent listing dispute communication should be directed to the Office of Generic Drugs, OGD Document Room, Attention: Orange Book Staff, 7620 Standish Pl., Rockville, MD 20855, or to the Orange Book Staff at the email address listed on the Agency's Web site at *http://www.fda.gov*.

(i) *Communication with the NDA holder*—(A) *Drug substance or drug product claim.* For requests submitted under this paragraph (f)(1) that are directed to the accuracy or relevance of submitted patent information regarding a drug substance or drug product claim, the Agency will send the statement of dispute to the applicable NDA holder. The NDA holder must confirm the correctness of the patent information and include the signed verification required by paragraph (c)(2)(ii)(R) of this section or withdraw or amend the patent information in accordance with paragraph (f)(2) of this section within 30 days of the date on which the Agency sends the statement of dispute. Unless the NDA holder withdraws or amends its patent information in response to the patent listing dispute, the Agency will not change the patent information in the Orange Book.

(B) *Method-of-use claim.* For requests submitted under this paragraph (f)(1) that are directed to the accuracy or relevance of submitted patent information regarding an approved method of using the drug product, FDA will send the statement of dispute to the NDA holder. The NDA holder must confirm the correctness of its description of the approved method of use claimed by the patent that has been included as the ''Use Code'' in the Orange Book, or withdraw or amend the patent information in accordance with paragraph (f)(2) of this section, provide a narrative description (no more than 250 words) of the NDA holder's

interpretation of the scope of the patent that explains why the existing or amended ''Use Code'' describes only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product, and include the signed verification required by paragraph (c)(2)(ii)(R) of this section within 30 days of the date on which the Agency sends the statement of dispute. The narrative description must only contain information for which the NDA holder consents to disclosure because FDA will send the text of the statement to the person who submitted the patent listing dispute without review or redaction.

(*1*) If the NDA holder confirms the correctness of the patent information, provides the narrative description required by paragraph (f)(1)(i)(B) of this section, and includes the signed verification required by paragraph (c)(2)(ii)(R) of this section within 30 days of the date on which the Agency sends the statement of dispute, the Agency will not change the patent information in the Orange Book.

(*2*) If the NDA holder responds to the patent listing dispute with amended patent information in accordance with paragraph (f)(2) of this section, provides the narrative description required by paragraph (f)(1)(i)(B) of this section, and includes the signed verification required by paragraph (c)(2)(ii)(R) of this section within 30 days of the date on which the Agency sends the statement of dispute, FDA will update the Orange Book to reflect the amended patent information.

(ii) *Patent certification or statement during and after patent listing dispute.* A 505(b)(2) application or ANDA must contain an appropriate certification or statement for each listed patent, including the disputed patent, during and after the patent listing dispute.

(iii) *Information on patent listing disputes.* FDA will promptly post information on its Web site regarding whether a patent listing dispute has been submitted for a published description of a patented method of use for a drug product and whether the NDA holder has timely responded to the patent listing dispute.

(2) *Requests by the NDA holder*—(i) *Patents or patent claims that no longer meet the statutory requirements for listing.* If the NDA holder determines that a patent or patent claim no longer meets the requirements for listing in section 505(b)(1) or (c)(2) of the Federal Food, Drug, and Cosmetic Act (including if there has been a judicial finding of invalidity for a listed patent, from which no appeal has been or can be taken), the NDA holder is required to promptly notify FDA to amend the patent information or withdraw the patent or patent information and request that the patent or patent information be removed from the list. If the NDA holder is required by court order to amend patent information or withdraw a patent from the list, it must submit an amendment to its NDA that includes a copy of the order, within 14 days of the date the order was entered, to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. The amendment to the NDA must bear the identification described in paragraph (d)(6) of this section. FDA will remove a patent or patent information from the list if there is no first applicant eligible for 180-day exclusivity based on a paragraph IV certification to that patent or after the 180-day exclusivity period of a first applicant based on that patent has expired or has been extinguished.

(ii) *Patent term restoration.* If the term of a listed patent is extended pursuant to 35 U.S.C. 156(e), the NDA holder must submit on Form FDA 3542 a correction to the expiration date of the patent. This correction must be submitted within 30 days of receipt of a certificate of extension as described in 35 U.S.C. 156(e)(1) or documentation of an extension of the term of the patent as described in 35 U.S.C. 156(e)(2).

(iii) *Submission of corrections or changes to patent information.* Corrections or changes to previously submitted patent information, other than withdrawal of a patent and requests to remove a patent from the list, must be submitted on Form FDA 3542 or 3542a, as appropriate, in an amendment or supplement to the NDA. The amendment or supplement to the NDA must bear the identification described in paragraph (d)(6) of this section. We will not accept the corrections or changes unless they are submitted on the appropriate forms.

(iv) *Submission of patent withdrawals and requests to remove a patent from the list.* Withdrawal of a patent and requests to remove a patent from the list must be submitted to the same addresses described in paragraph (d)(4)(ii) of this section, except that the withdrawal or request to remove a patent from the list is not required to be submitted on Form FDA 3542 and may be submitted by letter. Withdrawal of a patent and a request to remove a patent from the list must contain the following information:

(A) The NDA number to which the request applies;

(B) Each product(s) approved in the NDA to which the request applies; and

(C) The patent number.

■ 6. Amend § 314.54 as follows:

■ a. Remove the word ''shall'' and add in its place the word ''must'' in paragraph (a)(1) introductory text and paragraphs (a)(1)(i) and (a)(3); and

■ b. Revise the section heading, paragraph (a) introductory text, and paragraphs (a)(1)(iii), (v), and (vi), (a)(2) and (4), and (b).

The revisions read as follows:

§ 314.54 Procedure for submission of a 505(b)(2) application requiring investigations for approval of a new indication for, or other change from, a listed drug.

(a) The Federal Food, Drug, and Cosmetic Act does not permit approval of an ANDA for a new indication, nor does it permit approval of other changes in a listed drug if investigations, other than bioavailability or bioequivalence studies, are essential to the approval of the change. Any person seeking approval of a drug product that represents a modification of a listed drug (*e.g.,* a new indication or new dosage form) and for which investigations, other than bioavailability or bioequivalence studies, are essential to the approval of the changes may, except as provided in paragraph (b) of this section, submit a 505(b)(2) application. This 505(b)(2) application need contain only that information needed to support the modification(s) of the listed drug.

(1) * * *

(iii) Identification of each listed drug for which FDA has made a finding of safety and effectiveness and on which finding the applicant relies in seeking approval of its proposed drug product by established name, if any, proprietary name, dosage form, strength, route of administration, name of listed drug's application holder, and listed drug's approved NDA number. The listed drug(s) identified as relied upon must include a drug product approved in an NDA that:

(A) Is pharmaceutically equivalent to the drug product for which the original 505(b)(2) application is submitted; and

(B) Was approved before the original 505(b)(2) application was submitted.

* * * * *

(v) Any patent information required under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to any patent which claims the drug for which approval is sought or a method of using such drug and to which a claim of patent infringement could

reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.

(vi) Any patent certification or statement required under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act with respect to any relevant patents that claim the listed drug(s) on which investigations relied on by the applicant for approval of the application were conducted, or that claim a use for the listed drug(s). A 505(b)(2) applicant seeking approval of a drug that is pharmaceutically equivalent to a listed drug approved in an NDA implicitly relies upon one such pharmaceutically equivalent listed drug.

* * * * *

(2) The applicant must submit a review copy that contains the technical sections described in § 314.50(d)(1), except that the section described in § 314.50(d)(1)(ii)(*c*) must contain the proposed or actual master production record, including a description of the equipment, to be used for the manufacture of a commercial lot of the drug product, and § 314.50(d)(3), and the technical sections described in § 314.50(d)(2), (d)(4) through (6), and (f) when needed to support the modification. Each of the technical sections in the review copy is required to be separately bound with a copy of the information required under § 314.50(a), (b), and (c) and a copy of the proposed labeling.

* * * * *

(4) The applicant must submit a field copy of the 505(b)(2) application that contains the technical section described in § 314.50(d)(1), a copy of the information required under § 314.50(a) and (c), and certification that the field copy is a true copy of the technical section described in § 314.50(d)(1) contained in the archival and review copies of the 505(b)(2) application.

(b) A 505(b)(2) application may not be submitted under this section for a drug product whose only difference from a listed drug is that:

(1) The extent to which its active ingredient(s) is absorbed or otherwise made available to the site of action is less than that of the listed drug; or

(2) The rate at which its active ingredient(s) is absorbed or otherwise made available to the site of action is unintentionally less than that of the listed drug.

■ 7. Amend § 314.60 as follows:

■ a. Remove the word ''application'' and add in its place ''NDA'' wherever it appears;

■ b. Remove the word ''act'' and add in its place ''Federal Food, Drug, and Cosmetic Act'' wherever it appears in paragraphs (b)(1) and (4), (c)(1)(i), and (c)(2);

■ c. Remove ''505(c)(3)(D)(ii)'' and add in its place ''505(c)(3)(E)(ii)'' in paragraphs (c)(1)(i) and (c)(2);

■ d. Add paragraph headings in paragraphs (b) and (c);

■ e. Revise the section heading and paragraphs (a), (c)(1)(iii), and (d); and

■ f. Add paragraphs (e) and (f).

The revisions and additions read as follows:

§ 314.60 Amendments to an unapproved NDA, supplement, or resubmission.

(a) *Submission of NDA.* FDA generally assumes that when an original NDA, supplement to an approved NDA, or resubmission of an NDA or supplement is submitted to the Agency for review, the applicant believes that the Agency can approve the NDA, supplement, or resubmission as submitted. However, the applicant may submit an amendment to an NDA, supplement, or resubmission that has been filed under § 314.101 but is not yet approved.

(b) *Submission of major amendment.* * * *

(c) *Limitation on certain amendments.*

(1) * * *

(iii) The applicant has not obtained a right of reference or use to the investigation described in paragraph (c)(1)(ii) of this section; and

* * * * *

(d) *Field copy.* The applicant must submit a field copy of each amendment to a section of the NDA described in § 314.50(d)(1). The applicant must include in its submission of each such amendment to FDA a statement certifying that a field copy of the amendment has been sent to the applicant's home FDA district office.

(e) *Different drug.* An applicant may not amend a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the original submission of the 505(b)(2) application. For purposes of this paragraph (e), a drug is a different drug if it has been modified to have a different active ingredient, different route of administration, different dosage form, or difference in excipients that requires either a separate clinical study to establish safety or effectiveness or, for topical products, that requires a separate in vivo demonstration of bioequivalence. However, notwithstanding the limitation described in this paragraph (e), an applicant may amend the 505(b)(2) application to seek approval of a different strength.

(f) *Patent certification requirements.* (1) An amendment to a 505(b)(2) application is required to contain an appropriate patent certification or statement described in § 314.50(i) or a recertification for a previously submitted paragraph IV certification if approval is sought for any of the following types of amendments:

(i) To add a new indication or other condition of use;

(ii) To add a new strength;

(iii) To make other than minor changes in product formulation; or

(iv) To change the physical form or crystalline structure of the active ingredient.

(2) If the amendment to the 505(b)(2) application does not contain a patent certification or statement, the applicant must verify that the proposed change described in the amendment is not one of the types of amendments described in paragraph (f)(1) of this section.

■ 8. Amend § 314.70 as follows:

■ a. Remove the word ''application'' and add in its place ''NDA'' wherever it appears in the paragraph (a) heading and paragraphs (a)(1)(i) and (ii), (b)(2)(i) and (viii), (c)(6) introductory text, (c)(7), (d)(2)(v) through (vii), (d)(3)(i), and (e);

■ b. Remove the words ''cover letter'' and add in their place the word ''submission'' in paragraph (a)(6);

■ c. Remove the words ''and its mailing cover'' in paragraph (b)(4);

■ d. Revise the section heading and paragraphs (a)(2) and (f); and

■ e. Add paragraph (h).

The revisions and addition read as follows:

§ 314.70 Supplements and other changes to an approved NDA.

(a) * * *

(2) The NDA holder must assess the effects of the change before distributing a drug product made with a manufacturing change.

* * * * *

(f) *Patent information.* The applicant must comply with the patent information requirements under section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act and § 314.53.

* * * * *

(h) *Different drug.* An applicant may not supplement a 505(b)(2) application to seek approval of a drug that is a different drug from the drug in the approved 505(b)(2) application. For purposes of this paragraph (h), a drug is a different drug if it has been modified to have a different active ingredient, different route of administration, different dosage form, or difference in excipients that requires either a separate clinical study to establish safety or effectiveness or, for topical products, that requires a separate in vivo

demonstration of bioequivalence. However, notwithstanding the limitation described in this paragraph (h), an applicant may supplement the 505(b)(2) application to seek approval of a different strength.

■ 9. Amend § 314.90 by removing the word ''application'' and adding in its place ''NDA'' wherever it appears and adding paragraph (c) to read as follows:

§ 314.90 Waivers.

* * * * *

(c) If FDA grants the applicant's waiver request with respect to a requirement under §§ 314.50 through 314.81, the waived requirement will not constitute a basis for refusal to approve an NDA under § 314.125.

■ 10. Amend § 314.93 as follows:

■ a. Remove the words ''abbreviated new drug applications'' and add in their place ''ANDAs'' in paragraph (a);

■ b. Remove the words ''abbreviated new drug application'' and add in their place ''ANDA'' wherever they appear in paragraphs (b), (c), and (e)(3);

■ c. Remove the words ''abbreviated application'' and add in their place ''ANDA'' in paragraph (b);

■ d. Remove ''201(b)'' and add in its place ''201(p)'' in paragraph (d)(3);

■ e. Remove the word ''act'' and add in its place ''Federal Food, Drug, and Cosmetic Act'' in paragraphs (d)(3) and (e)(1)(iii)(C);

■ f. Remove the period at the end of paragraph (e)(1)(v) and add in its place ''; or'';

■ g. Add paragraph (e)(1)(vi);

■ h. Redesignate paragraph (f) as paragraph (f)(1); and

■ i. Add paragraph (f)(2).

The revisions and additions read as follows:

§ 314.93 Petition to request a change from a listed drug.

* * * * *

(e) * * *

(1) * * *

(vi) A drug product is approved in an NDA for the change described in the petition.

* * * * *

(f) * * *

(2) If, after approval of a petition and before approval of an ANDA submitted pursuant to the approved petition, a drug product is approved in an NDA for the change described in the petition, the petition and the listed drug identified in the petition can no longer be the basis for ANDA submission, irrespective of whether FDA has withdrawn approval of the petition. A person seeking approval for such drug product must submit a new ANDA that identifies the pharmaceutically equivalent reference listed drug as the basis for ANDA submission and comply with applicable regulatory requirements.

■ 11. Amend § 314.94 as follows:

■ a. Remove the words ''abbreviated application'' and add in their place ''ANDA'' wherever they appear in paragraphs (a)(1), (a)(5)(ii)(A), (a)(6)(ii), (a)(9)(v), (a)(12)(i)(A)(*4*), (a)(13), (d)(1)(i), (d)(4), and (d)(5);

■ b. Remove the words ''abbreviated new drug application'' and add in their place ''ANDA'' wherever they appear in paragraph (a) introductory text and paragraphs (a)(8)(i) and (b);

■ c. Remove the word ''shall'' and add in its place the word ''must'' wherever it appears in paragraph (a) introductory text and paragraphs (a)(1), (a)(9)(ii) through (iv), (a)(12)(i)(A)(*1*) through (*3*), (a)(13), (b), and (d)(5);

■ d. Remove the word ''act'' and add in its place ''Federal Food, Drug, and Cosmetic Act'' wherever it appears in paragraphs (a)(5)(ii)(A), (a)(7)(ii)(C), and (a)(8)(iv);

■ e. Remove ''§ 320.1(g) of this chapter'' and add in its place ''§ 314.3(b)'' in paragraph (a)(7)(i);

■ f. Remove and reserve paragraph (a)(12)(iv); and

■ g. Revise the section heading and the introductory text, paragraph (a) heading, paragraph (a)(2), paragraph (a)(3), the first sentence of paragraph (a)(7)(ii) introductory text, paragraphs (a)(7)(iii) and (a)(9)(i), paragraph (a)(12)(i) heading, paragraph (a)(12)(i)(A) introductory text, paragraphs (a)(12)(i)(A)(*4*), (a)(12)(i)(B), (a)(12)(ii) and (iii), (a)(12)(iv) through (viii), paragraph (d) heading, paragraph (d)(1) introductory text, and paragraph (d)(2).

The revisions read as follows:

§ 314.94 Content and format of an ANDA.

ANDAs are required to be submitted in the form and contain the information required under this section. Three copies of the ANDA are required, an archival copy, a review copy, and a field copy. FDA will maintain guidance documents on the format and content of ANDAs to assist applicants in their preparation.

(a) *ANDAs.* * * *

* * * * *

(2) *Table of contents.* The archival copy of the ANDA is required to contain a table of contents that shows the volume number and page number of the contents of the submission.

(3) *Basis for ANDA submission.* An ANDA must refer to a listed drug. Ordinarily, that listed drug will be the drug product selected by the Agency as the reference standard for conducting bioequivalence testing. The ANDA must contain:

(i) The name of the reference listed drug, including its dosage form and strength. For an ANDA based on an approved petition under § 10.30 of this chapter and § 314.93, the reference listed drug must be the same as the listed drug referenced in the approved petition.

(ii) A statement as to whether, according to the information published in the list, the reference listed drug is entitled to a period of marketing exclusivity under section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act.

(iii) For an ANDA based on an approved petition under § 10.30 of this chapter and § 314.93, a reference to the FDA-assigned docket number for the petition and a copy of FDA's correspondence approving the petition.

* * * * *

(7) * * *

(ii) If the ANDA is submitted pursuant to a petition approved under § 314.93, the results of any bioavailability or bioequivalence testing required by the Agency, or any other information required by the Agency to show that the active ingredients of the proposed drug product are of the same pharmacological or therapeutic class as those in the reference listed drug and that the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug. * * *

* * * * *

(iii) For each in vivo or in vitro bioequivalence study contained in the ANDA:

(A) A description of the analytical and statistical methods used in each study; and

(B) With respect to each study involving human subjects, a statement that the study either was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to the regulations under § 56.104 or § 56.105 of this chapter, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter.

* * * * *

(9) * * *

(i) The information required under § 314.50(d)(1), except that the information required under § 314.50(d)(1)(ii)(*c*) must contain the proposed or actual master production record, including a description of the equipment, to be used for the manufacture of a commercial lot of the drug product.

* * * * *

(12) *Patent certification*—(i) *Patents claiming drug substance, drug product,*

or method of use. (A) An appropriate patent certification or statement with respect to each patent issued by the U.S. Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims the reference listed drug or that claims a use of such listed drug for which the applicant is seeking approval under section 505(j) of the Federal Food, Drug, and Cosmetic Act and for which information is required to be filed under section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53. For each such patent, the applicant must provide the patent number and certify, in its opinion and to the best of its knowledge, one of the following circumstances:

* * * * *

(*4*)(*i*) That the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. The applicant must entitle such a certification ''Paragraph IV Certification''. This certification must be submitted in the following form:

I, (*name of applicant),* certify that Patent No. _____((*is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of*) (*name of proposed drug product*) for which this ANDA is submitted.

(*ii*) The certification must be accompanied by a statement that the applicant will comply with the requirements under § 314.95(a) with respect to providing a notice to each owner of the patent or its representative and to the NDA holder (or, if the NDA holder does not reside or maintain a place of business within the United States, its attorney, agent, or other authorized official) for the listed drug, with the requirements under § 314.95(b) with respect to sending the notice, and with the requirements under § 314.95(c) with respect to the content of the notice.

(B) If the ANDA refers to a listed drug that is itself a licensed generic product of a patented drug first approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act, an appropriate patent certification or statement under paragraph (a)(12)(i) and/or (iii) of this section with respect to each patent that claims the first-approved patented drug or that claims a use for such drug.

(ii) *No relevant patents.* If, in the opinion of the applicant and to the best of its knowledge, there are no patents described in paragraph (a)(12)(i) of this section, a certification in the following form:

In the opinion and to the best knowledge of (name of applicant), there are no patents that claim the listed drug referred to in this ANDA or that claim a use of the listed drug.

(iii) *Method-of-use patent.* (A) If patent information is submitted under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53 for a patent claiming a method of using the listed drug, and the labeling for the drug product for which the applicant is seeking approval does not include an indication or other condition of use that is covered by the method-of-use patent, a statement explaining that the method-of-use patent does not claim a proposed indication or other condition of use.

(B) If the labeling of the drug product for which the applicant is seeking approval includes an indication or other condition of use that, according to the patent information submitted under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53 or in the opinion of the applicant, is claimed by a method-of-use patent, an applicable certification under paragraph (a)(12)(i) of this section.

(iv) [Reserved]

(v) *Licensing agreements.* If the ANDA is for a drug or method of using a drug claimed by a patent and the applicant has a licensing agreement with the patent owner, the applicant must submit a paragraph IV certification as to that patent and a statement that the applicant has been granted a patent license. If the patent owner consents to approval of the ANDA (if otherwise eligible for approval) as of a specific date, the ANDA must contain a written statement from the patent owner that it has a licensing agreement with the applicant and that it consents to approval of the ANDA as of a specific date.

(vi) *Untimely filing of patent information.* (A) If a patent on the listed drug is issued and the holder of the approved NDA for the listed drug does not file with FDA the required information on the patent within 30 days of issuance of the patent, an applicant who submitted an ANDA for that drug that contained an appropriate patent certification or statement before the submission of the patent information is not required to submit a patent certification or statement to address the patent or patent information that is late-listed with respect to the pending ANDA. Except as provided in § 314.53(f)(1), an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent will be considered untimely filing of patent information unless:

(*1*) The amendment to the description of the approved method(s) of use claimed by the patent is submitted within 30 days of patent issuance;

(*2*) The amendment to the description of the approved method(s) of use claimed by the patent is submitted within 30 days of approval of a corresponding change to product labeling; or

(*3*) The amendment to the description of the approved method(s) of use claimed by the patent is submitted within 30 days of a decision by the U.S. Patent and Trademark Office or by a Federal district court, the Court of Appeals for the Federal Circuit, or the U.S. Supreme Court that is specific to the patent and alters the construction of a method-of-use claim(s) of the patent, and the amendment contains a copy of the decision.

(B) An applicant whose ANDA is submitted after the NDA holder's untimely filing of patent information, or whose pending ANDA was previously submitted but did not contain an appropriate patent certification or statement at the time of the patent submission, must submit a certification under paragraph (a)(12)(i) of this section and/or a statement under paragraph (a)(12)(iii) of this section as to that patent.

(vii) *Disputed patent information.* If an applicant disputes the accuracy or relevance of patent information submitted to FDA, the applicant may seek a confirmation of the correctness of the patent information in accordance with the procedures under § 314.53(f). Unless the patent information is withdrawn, the applicant must submit an appropriate certification or statement for each listed patent.

(viii) *Amended certifications.* A patent certification or statement submitted under paragraphs (a)(12)(i) through (iii) of this section may be amended at any time before the approval of the ANDA. If an applicant with a pending ANDA voluntarily makes a patent certification for an untimely filed patent, the applicant may withdraw the patent certification for the untimely filed patent. An applicant must submit an amended certification as an amendment to a pending ANDA. Once an amendment is submitted to change a certification, the ANDA will no longer be considered to contain the prior certification.

(A) *After finding of infringement.* An applicant who has submitted a paragraph IV certification and is sued for patent infringement must submit an amendment to change its certification if a court enters a final decision from which no appeal has been or can be taken, or signs and enters a settlement order or consent decree in the action that includes a finding that the patent is infringed, unless the final decision, settlement order, or consent decree also finds the patent to be invalid. In its

amendment, the applicant must certify under paragraph (a)(12)(i)(A)(*3*) of this section that the patent will expire on a specific date or, with respect to a patent claiming a method of use, the applicant may instead provide a statement under paragraph (a)(12)(iii) of this section if the applicant amends its ANDA such that the applicant is no longer seeking approval for a method of use claimed by the patent. Once an amendment for the change has been submitted, the ANDA will no longer be considered to contain a paragraph IV certification to the patent. If a final judgment finds the patent to be invalid and infringed, an amended certification is not required.

(B) *After request to remove a patent or patent information from the list.* If the list reflects that an NDA holder has requested that a patent or patent information be removed from the list and no ANDA applicant is eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent or patent information will be removed and any applicant with a pending ANDA (including a tentatively approved ANDA) who has made a certification with respect to such patent must submit an amendment to withdraw its certification. In the amendment, the applicant must state the reason for withdrawing the certification or statement (that the patent has been removed from the list). If the list reflects that an NDA holder has requested that a patent or patent information be removed from the list and one or more first applicants are eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent will remain listed until any 180-day exclusivity based on that patent has expired or has been extinguished. After any applicable 180-day exclusivity has expired or has been extinguished, the patent or patent information will be removed and any applicant with a pending ANDA (including a tentatively approved ANDA) who has made a certification with respect to such patent must submit an amendment to withdraw its certification. Once an amendment to withdraw the certification has been submitted, the ANDA will no longer be considered to contain a paragraph IV certification to the patent. If removal of a patent from the list results in there being no patents listed for the listed drug identified in the ANDA, the applicant must submit an amended certification reflecting that there are no relevant patents.

(C) *Other amendments.* (*1*) Except as provided in paragraphs (a)(12)(vi) and (a)(12)(viii)(C)(*2*) of this section:

(*i*) An applicant must amend a submitted certification or statement if, at any time before the date of approval of the ANDA, the applicant learns that the submitted certification or statement is no longer accurate; and

(*ii*) An applicant must submit an appropriate patent certification or statement under paragraph (a)(12)(i) and/or (iii) of this section if, after submission of the ANDA, a new patent is issued by the U.S. Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims the reference listed drug or that claims an approved use for such reference listed drug and for which information is required to be filed under section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53. For a paragraph IV certification, the certification must not be submitted earlier than the first working day after the day the patent is published in the list.

(*2*) An applicant is not required to submit a supplement to change a submitted certification when information on a patent on the listed drug is submitted after the approval of the ANDA.

* * * * *

(d) *Format of an ANDA.* (1) The applicant must submit a complete archival copy of the ANDA as required under paragraphs (a) and (c) of this section. FDA will maintain the archival copy during the review of the ANDA to permit individual reviewers to refer to information that is not contained in their particular technical sections of the ANDA, to give other Agency personnel access to the ANDA for official business, and to maintain in one place a complete copy of the ANDA.

* * * * *

(2) For ANDAs, the applicant must submit a review copy of the ANDA that contains two separate sections. One section must contain the information described under paragraphs (a)(2) through (6) and (8) and (9) of this section and section 505(j)(2)(A)(vii) of the Federal Food, Drug, and Cosmetic Act and a copy of the analytical procedures and descriptive information needed by FDA's laboratories to perform tests on samples of the proposed drug product and to validate the applicant's analytical procedures. The other section must contain the information described under paragraphs (a)(3), (7), and (8) of this section. Each of the sections in the review copy is required to contain a copy of the application form described under paragraph (a) of this section.

* * * * *

■ 12. Section 314.95 is revised to read as follows:

§ 314.95 Notice of certification of invalidity, unenforceability, or noninfringement of a patent.

(a) *Notice of certification.* For each patent that claims the listed drug or that claims a use for such listed drug for which the applicant is seeking approval and for which the applicant submits a paragraph IV certification, the applicant must send notice of such certification by registered or certified mail, return receipt requested, or by a designated delivery service, as defined in paragraph (g) of this section to each of the following persons:

(1) Each owner of the patent that is the subject of the certification or the representative designated by the owner to receive the notice. The name and address of the patent owner or its representative may be obtained from the U.S. Patent and Trademark Office; and

(2) The holder of the approved NDA under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the listed drug that is claimed by the patent and for which the applicant is seeking approval, or, if the NDA holder does not reside or maintain a place of business within the United States, the NDA holder's attorney, agent, or other authorized official. The name and address of the NDA holder or its attorney, agent, or authorized official may be obtained by sending a written or electronic communication to the Orange Book Staff, Office of Generic Drugs, 7620 Standish Pl., Rockville, MD 20855 or to the Orange Book Staff at the email address listed on the Agency's Web site at *http://www.fda.gov*.

(3) This paragraph (a) does not apply to a method-of-use patent that does not claim a use for which the applicant is seeking approval.

(4) An applicant may send notice by an alternative method only if FDA has agreed in advance that the method will produce an acceptable form of documentation.

(b) *Sending the notice.* (1) Except as provided under paragraph (d) of this section, the applicant must send the notice required by paragraph (a) of this section on or after the date it receives a paragraph IV acknowledgment letter from FDA, but not later than 20 days after the date of the postmark on the paragraph IV acknowledgment letter. The 20-day clock described in this paragraph (b) begins on the day after the date of the postmark on the paragraph IV acknowledgment letter. When the 20th day falls on Saturday, Sunday, or a Federal holiday, the 20th day will be

the next day that is not a Saturday, Sunday, or Federal holiday.

(2) Any notice required by paragraph (a) of this section is invalid if it is sent before the applicant's receipt of a paragraph IV acknowledgment letter, or before the first working day after the day the patent is published in the list. The applicant will not have complied with this paragraph (b) until it sends valid notice.

(3) The applicant must submit to FDA an amendment to its ANDA that includes a statement certifying that the notice has been provided to each person identified under paragraph (a) of this section and that the notice met the content requirements under paragraph (c) of this section. A copy of the notice itself need not be submitted to the Agency.

(c) *Contents of a notice.* In the notice, the applicant must cite section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and the notice must include, but is not limited to, the following information:

(1) A statement that FDA has received an ANDA submitted by the applicant containing any required bioavailability or bioequivalence data or information.

(2) The ANDA number.

(3) A statement that the applicant has received the paragraph IV acknowledgment letter for the ANDA.

(4) The established name, if any, as defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act, of the proposed drug product.

(5) The active ingredient, strength, and dosage form of the proposed drug product.

(6) The patent number and expiration date of each listed patent for the reference listed drug alleged to be invalid, unenforceable, or not infringed.

(7) A detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed. The applicant must include in the detailed statement:

(i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed.

(ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.

(8) If the applicant alleges that the patent will not be infringed and the applicant seeks to preserve the option to later file a civil action for declaratory judgment in accordance with section 505(j)(5)(C) of the Federal Food, Drug, and Cosmetic Act, then the notice must be accompanied by an offer of confidential access to the ANDA for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the paragraph IV certification.

(9) If the applicant does not reside or have a place of business in the United States, the name and address of an agent in the United States authorized to accept service of process for the applicant.

(d) *Amendment or supplement to an ANDA.* (1) If, after receipt of a paragraph IV acknowledgment letter or acknowledgment letter, an applicant submits an amendment or supplement to its ANDA that includes a paragraph IV certification, the applicant must send the notice required by paragraph (a) of this section at the same time that the amendment or supplement to the ANDA is submitted to FDA, regardless of whether the applicant has already given notice with respect to another such certification contained in the ANDA or in an amendment or supplement to the ANDA.

(2) If, before receipt of a paragraph IV acknowledgment letter, an applicant submits an amendment to its ANDA that includes a paragraph IV certification, the applicant must send the notice required by paragraph (a) of this section in accordance with the procedures in paragraph (b) of this section. If an ANDA applicant's notice of its paragraph IV certification is timely provided in accordance with paragraph (b) of this section and the applicant has not submitted a previous paragraph IV certification, FDA will base its determination of whether the applicant is a first applicant on the date of submission of the amendment containing the paragraph IV certification.

(3) An applicant that submits an amendment or supplement to seek approval of a different strength must provide notice of any paragraph IV certification in accordance with paragraph (d)(1) or (2) of this section, as applicable.

(e) *Documentation of timely sending and receipt of notice.* The applicant must amend its ANDA to provide documentation of the date of receipt of the notice required under paragraph (a) of this section by each person provided the notice. The amendment must be submitted to FDA within 30 days after the last date on which notice was received by a person described in paragraph (a) of this section. The applicant's amendment also must include documentation that its notice was sent on a date that complies with the timeframe required by paragraph (b) or (d) of this section, as applicable, and a dated printout of the entry for the reference listed drug in FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (the list) that includes the patent that is the subject of the paragraph IV certification. FDA will accept, as adequate documentation of the date the notice was sent, a copy of the registered mail receipt, certified mail receipt, or receipt from a designated delivery service as defined in paragraph (g) of this section. FDA will accept as adequate documentation of the date of receipt a return receipt, signature proof of delivery by a designated delivery service, or a letter acknowledging receipt by the person provided the notice. An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance. A copy of the notice itself need not be submitted to the Agency.

(f) *Forty-five day period after receipt of notice.* If the requirements of this section are met, FDA will presume the notice to be complete and sufficient, and it will count the day following the date of receipt of the notice by the patent owner or its representative and by the approved NDA holder or its attorney, agent, or other authorized official as the first day of the 45-day period provided for in section 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act. FDA may, if the applicant provides a written statement to FDA that a later date should be used, count from such later date.

(g) *Designated delivery services.* (1) For purposes of this section, the term ''designated delivery service'' means any delivery service provided by a trade or business that the Agency determines:

(i) Is available to the general public throughout the United States;

(ii) Records electronically to its database, kept in the regular course of its business, or marks on the cover in which any item referred to in this section is to be delivered, the date on which such item was given to such trade or business for delivery; and

(iii) Provides overnight or 2-day delivery service throughout the United States.

(2) FDA may periodically issue guidance regarding designated delivery services.

■ 13. Amend § 314.96 as follows:

■ a. Revise the section heading;

■ b. Remove the words ''abbreviated new drug application'' and add in their place ''ANDA'' in the paragraph (a) heading and the first two sentences of paragraph (a)(1);

■ c. Remove ''320.1(g) of this chapter'' and add in its place ''314.3'' in paragraph (a)(1);

■ d. Remove the word ''shall'' and add in its place the word ''must'' wherever it appears and remove ''to § 314.94(a)(9)'' and add in its place ''under § 314.94(a)(9)'' in paragraph (b);
■ e. Add a heading to paragraph (b); and
■ f. Add paragraphs (c) and (d).

The revisions and additions read as follows:

§ 314.96 Amendments to an unapproved ANDA.

* * * * *

(b) *Field copy.* * * *

(c) *Different listed drug.* An applicant may not amend an ANDA to seek approval of a drug referring to a listed drug that is different from the reference listed drug identified in the ANDA. This paragraph (c) applies if, at any time before the approval of the ANDA, a different listed drug is approved that is the pharmaceutical equivalent to the product in the ANDA and is designated as a reference listed drug. This paragraph (c) also applies if changes are proposed in an amendment to the ANDA such that the proposed product is a pharmaceutical equivalent to a different listed drug than the reference listed drug identified in the ANDA. A change of the reference listed drug must be submitted in a new ANDA. However, notwithstanding the limitation described in this paragraph (c), an applicant may amend the ANDA to seek approval of a different strength.

(d)(1) *Patent certification requirements.* An amendment to an ANDA is required to contain an appropriate patent certification or statement described in § 314.94(a)(12) or a recertification for a previously submitted paragraph IV certification if approval is sought for any of the following types of amendments:

(i) To add a new indication or other condition of use;

(ii) To add a new strength;

(iii) To make other than minor changes in product formulation; or

(iv) To change the physical form or crystalline structure of the active ingredient.

(2) If the amendment to the ANDA does not contain a patent certification or statement, the applicant must verify that the proposed change described in the amendment is not one of the types of amendments described in paragraph (d)(1) of this section.

■ 14. Section 314.97 is revised to read as follows:

§ 314.97 Supplements and other changes to an approved ANDA.

(a) *General requirements.* The applicant must comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental ANDAs and other changes to an approved ANDA.

(b) *Different listed drug.* An applicant may not supplement an ANDA to seek approval of a drug referring to a listed drug that is different from the current reference listed drug identified in the ANDA. This paragraph (b) applies if changes are proposed in a supplement to the ANDA such that the proposed product is a pharmaceutical equivalent to a different listed drug than the reference listed drug identified in the ANDA. A change of reference listed drug must be submitted in a new ANDA. However, notwithstanding the limitation described in this paragraph (b), an applicant may supplement the ANDA to seek approval of a different strength.

■ 15. Section 314.99 is revised to read as follows:

§ 314.99 Other responsibilities of an applicant of an ANDA.

(a) An applicant must comply with the requirements of § 314.65 regarding withdrawal by the applicant of an unapproved ANDA and § 314.72 regarding a change in ownership of an ANDA.

(b) An applicant may ask FDA to waive under this section any requirement that applies to the applicant under §§ 314.92 through 314.99. The applicant must comply with the requirements for a waiver under § 314.90. If FDA grants the applicant's waiver request with respect to a requirement under §§ 314.92 through 314.99, the waived requirement will not constitute a basis for refusal to approve an ANDA under § 314.127.

■ 16. Section 314.101 is revised to read as follows:

§ 314.101 Filing an NDA and receiving an ANDA.

(a) *Filing an NDA.* (1) Within 60 days after FDA receives an NDA, the Agency will determine whether the NDA may be filed. The filing of an NDA means that FDA has made a threshold determination that the NDA is sufficiently complete to permit a substantive review.

(2) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for refusing to file the NDA apply, the Agency will file the NDA and notify the applicant in writing. In the case of a 505(b)(2) application that contains a paragraph IV certification, the applicant will be notified via a paragraph IV acknowledgment letter. The date of filing will be the date 60 days after the date FDA received the NDA. The date of filing begins the 180-day period described in section 505(c) of the Federal Food, Drug, and Cosmetic Act. This 180-day period is called the ''filing clock.''

(3) If FDA refuses to file the NDA, the Agency will notify the applicant in writing and state the reason under paragraph (d) or (e) of this section for the refusal. If FDA refuses to file the NDA under paragraph (d) of this section, the applicant may request in writing within 30 days of the date of the Agency's notification an informal conference with the Agency about whether the Agency should file the NDA. If, following the informal conference, the applicant requests that FDA file the NDA (with or without amendments to correct the deficiencies), the Agency will file the NDA over protest under paragraph (a)(2) of this section, notify the applicant in writing, and review it as filed. If the NDA is filed over protest, the date of filing will be the date 60 days after the date the applicant requested the informal conference. The applicant need not resubmit a copy of an NDA that is filed over protest. If FDA refuses to file the NDA under paragraph (e) of this section, the applicant may amend the NDA and resubmit it, and the Agency will make a determination under this section whether it may be filed.

(b)(1) *Receiving an ANDA.* An ANDA will be evaluated after it is submitted to determine whether the ANDA may be received. Receipt of an ANDA means that FDA has made a threshold determination that the abbreviated application is substantially complete.

(2) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for considering the ANDA not to have been received applies, the ANDA is substantially complete and the Agency will receive the ANDA and notify the applicant in writing. If FDA determines, upon evaluation, that an ANDA was substantially complete as of the date it was submitted to FDA, FDA will consider the ANDA to have been received as of the date of submission. In the case of an ANDA that contains a paragraph IV certification, the applicant will be notified via a paragraph IV acknowledgment letter.

(3) If FDA considers the ANDA not to have been received under paragraph (d) or (e) of this section, FDA will notify the applicant of the refuse-to-receive decision. The applicant may then:

(i) Withdraw the ANDA under § 314.99; or

(ii) Correct the deficiencies and resubmit the ANDA; or

(iii) Take no action, in which case FDA may consider the ANDA withdrawn after 1 year.

(c) [Reserved]

(d) *NDA or ANDA deficiencies.* FDA may refuse to file an NDA or may not consider an ANDA to be received if any of the following applies:

(1) The NDA or ANDA does not contain a completed application form.

(2) The NDA or ANDA is not submitted in the form required under § 314.50 or § 314.94.

(3) The NDA or ANDA is incomplete because it does not on its face contain information required under section 505(b) or section 505(j) of the Federal Food, Drug, and Cosmetic Act and § 314.50 or § 314.94. In determining whether an ANDA is incomplete on its face, FDA will consider the nature (*e.g.,* major or minor) of the deficiencies, including the number of deficiencies in the ANDA.

(4) The applicant fails to submit a complete environmental assessment, which addresses each of the items specified in the applicable format under § 25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.30 or § 25.31 of this chapter.

(5) The NDA or ANDA does not contain an accurate and complete English translation of each part of the NDA or ANDA that is not in English.

(6) The NDA or ANDA does not contain a statement for each nonclinical laboratory study that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, for each study not conducted in compliance with part 58 of this chapter, a brief statement of the reason for the noncompliance.

(7) The NDA or ANDA does not contain a statement for each clinical study that the study was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to those regulations, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter, or, if the study was subject to but was not conducted in compliance with those regulations, the NDA or ANDA does not contain a brief statement of the reason for the noncompliance.

(8) The drug product that is the subject of the submission is already covered by an approved NDA or ANDA and the applicant of the submission:

(i) Has an approved NDA or ANDA for the same drug product; or

(ii) Is merely a distributor and/or repackager of the already approved drug product.

(9) The NDA is submitted as a 505(b)(2) application for a drug that is a duplicate of a listed drug and is eligible for approval under section 505(j) of the Federal Food, Drug, and Cosmetic Act.

(e) *Regulatory deficiencies.* The Agency will refuse to file an NDA or will consider an ANDA not to have been received if any of the following applies:

(1) The drug product is subject to licensing by FDA under the Public Health Service Act (42 U.S.C. 201 *et seq.*) and subchapter F of this chapter.

(2) Submission of a 505(b)(2) application or an ANDA is not permitted under section 505(c)(3)(E)(ii), 505(j)(5)(F)(ii), 505A(b)(1)(A)(i)(I), 505A(c)(1)(A)(i)(I), or 505E(a) of the Federal Food, Drug, and Cosmetic Act.

(f) *Outcome of FDA review.* (1) Within 180 days after the date of filing, plus the period of time the review period was extended (if any), FDA will either:

(i) Approve the NDA; or

(ii) Issue a notice of opportunity for a hearing if the applicant asked FDA to provide it an opportunity for a hearing on an NDA in response to a complete response letter.

(2) Within 180 days after the date of receipt, plus the period of time the review clock was extended (if any), FDA will either approve or disapprove the ANDA. If FDA disapproves the ANDA, FDA will issue a notice of opportunity for hearing if the applicant asked FDA to provide it an opportunity for a hearing on an ANDA in response to a complete response letter.

(3) This paragraph (f) does not apply to NDAs or ANDAs that have been withdrawn from FDA review by the applicant.

■ 17. Section 314.105 is revised to read as follows:

§ 314.105 Approval of an NDA and an ANDA.

(a) FDA will approve an NDA and send the applicant an approval letter if none of the reasons in § 314.125 for refusing to approve the NDA applies. FDA will issue a tentative approval letter if an NDA otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved because there is a 7-year period of orphan exclusivity for the listed drug under section 527 of the Federal Food, Drug, and Cosmetic Act and § 316.31 of this chapter, or if a 505(b)(2) application otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved until the conditions in § 314.107(b)(3) are met; because there is a period of exclusivity for the listed drug under § 314.108; because there is a period of pediatric exclusivity for the listed drug under section 505A of the Federal Food, Drug, and Cosmetic Act; or because there is a period of exclusivity for the listed drug under section 505E of the Federal Food, Drug, and Cosmetic Act. A drug product that is granted tentative approval is not an approved drug and will not be approved until FDA issues an approval after any necessary additional review of the NDA. FDA's tentative approval of a drug product is based on information available to FDA at the time of the tentative approval letter (*i.e.,* information in the 505(b)(2) application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA's attention. A new drug product may not be marketed until the date of approval.

(b) FDA will approve an NDA and issue the applicant an approval letter on the basis of draft labeling if the only deficiencies in the NDA concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.

(c) FDA will approve an NDA after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling, and an ANDA after it determines that the drug meets the statutory standards for manufacturing and controls, labeling, and, where applicable, bioequivalence. While the statutory standards apply to all drugs, the many kinds of drugs that are subject to the statutory standards and the wide range of uses for those drugs demand flexibility in applying the standards. Thus FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards. FDA makes its views on drug products and classes of drugs available through guidance documents, recommendations, and other statements of policy.

(d) FDA will approve an ANDA and send the applicant an approval letter if none of the reasons in § 314.127 for refusing to approve the ANDA applies. FDA will issue a tentative approval letter if an ANDA otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act, but cannot be approved because there is a 7-year period of orphan exclusivity for the listed drug under section 527 of the

Federal Food, Drug, and Cosmetic Act and § 316.31 of this chapter, or cannot be approved until the conditions in § 314.107(b)(3) or (c) are met; because there is a period of exclusivity for the listed drug under § 314.108; because there is a period of pediatric exclusivity for the listed drug under section 505A of the Federal Food, Drug, and Cosmetic Act; or because there is a period of exclusivity for the listed drug under section 505E of the Federal Food, Drug, and Cosmetic Act. A drug product that is granted tentative approval is not an approved drug and will not be approved until FDA issues an approval after any necessary additional review of the ANDA. FDA's tentative approval of a drug product is based on information available to FDA at the time of the tentative approval letter (*i.e.,* information in the ANDA and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA's attention. A new drug product may not be marketed until the date of approval.

■ 18. Section 314.107 is revised to read as follows:

§ 314.107 Date of approval of a 505(b)(2) application or ANDA.

(a) *General.* A drug product may be introduced or delivered for introduction into interstate commerce when the 505(b)(2) application or ANDA for the drug product is approved. A 505(b)(2) application or ANDA for a drug product is approved on the date FDA issues an approval letter under § 314.105 for the 505(b)(2) application or ANDA.

(b) *Effect of patent(s) on the listed drug.* As described in paragraphs (b)(1) and (2) of this section, the status of patents listed for the listed drug(s) relied upon or reference listed drug, as applicable, must be considered in determining the first possible date on which a 505(b)(2) application or ANDA can be approved. The criteria in paragraphs (b)(1) and (2) of this section will be used to determine, for each relevant patent, the date that patent will no longer prevent approval. The first possible date on which the 505(b)(2) application or ANDA can be approved will be calculated for each patent, and the 505(b)(2) application or ANDA may be approved on the last applicable date.

(1) *Timing of approval based on patent certification or statement.* If none of the reasons in § 314.125 or § 314.127, as applicable, for refusing to approve the 505(b)(2) application or ANDA applies, and none of the reasons in paragraph (d) of this section for delaying approval applies, the 505(b)(2) application or ANDA may be approved as follows:

(i) Immediately, if the applicant certifies under § 314.50(i) or § 314.94(a)(12) that:

(A) The applicant is aware of a relevant patent but the patent information required under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act has not been submitted to FDA; or

(B) The relevant patent has expired; or

(C) The relevant patent is invalid, unenforceable, or will not be infringed, except as provided in paragraphs (b)(3) and (c) of this section, and the 45-day period provided for in section 505(c)(3)(C) and (j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act has expired; or

(D) There are no relevant patents.

(ii) Immediately, if the applicant submits an appropriate statement under § 314.50(i) or § 314.94(a)(12) explaining that a method-of-use patent does not claim an indication or other condition of use for which the applicant is seeking approval, except that if the applicant also submits a paragraph IV certification to the patent, then the 505(b)(2) application or ANDA may be approved as provided in paragraph (b)(1)(i)(C) of this section.

(iii) On the date specified, if the applicant certifies under § 314.50(i) or § 314.94(a)(12) that the relevant patent will expire on a specified date.

(2) *Patent information filed after submission of 505(b)(2) application or ANDA.* If the holder of the approved NDA for the listed drug submits patent information required under § 314.53 after the date on which the 505(b)(2) application or ANDA was submitted to FDA, the 505(b)(2) applicant or ANDA applicant must comply with the requirements of § 314.50(i)(4) and (6) and § 314.94(a)(12)(vi) and (viii) regarding submission of an appropriate patent certification or statement. If the applicant submits an amendment certifying under § 314.50(i)(1)(i)(A)(*4*) or § 314.94(a)(12)(i)(A)(*4*) that the relevant patent is invalid, unenforceable, or will not be infringed, and complies with the requirements of § 314.52 or § 314.95, the 505(b)(2) application or ANDA may be approved immediately upon submission of documentation of receipt of notice of paragraph IV certification under § 314.52(e) or § 314.95(e). The 45-day period provided for in section 505(c)(3)(C) and (j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act does not apply in these circumstances.

(3) *Disposition of patent litigation*—(i) *Approval upon expiration of 30-month period or 7½ years from date of listed drug approval.* (A) Except as provided in paragraphs (b)(3)(ii) through (viii) of this section, if, with respect to patents for which required information was submitted under § 314.53 before the date on which the 505(b)(2) application or ANDA was submitted to FDA (excluding an amendment or supplement to the 505(b)(2) application or ANDA), the applicant certifies under § 314.50(i) or § 314.94(a)(12) that the relevant patent is invalid, unenforceable, or will not be infringed, and the patent owner or its representative or the exclusive patent licensee brings suit for patent infringement within 45 days of receipt of the notice of certification from the applicant under § 314.52 or § 314.95, the 505(b)(2) application or ANDA may be approved 30 months after the later of the date of the receipt of the notice of certification by any owner of the listed patent or by the NDA holder (or its representative(s)) unless the court has extended or reduced the period because of a failure of either the plaintiff or defendant to cooperate reasonably in expediting the action; or

(B) If the patented drug product qualifies for 5 years of exclusive marketing under § 314.108(b)(2) and the patent owner or its representative or the exclusive patent licensee brings suit for patent infringement during the 1-year period beginning 4 years after the date of approval of the patented drug and within 45 days of receipt of the notice of certification from the applicant under § 314.52 or § 314.95, the 505(b)(2) application or ANDA may be approved at the expiration of the 7½ years from the date of approval of the NDA for the patented drug product.

(ii) *Federal district court decision of invalidity, unenforceability, or non-infringement.* If before the expiration of the 30-month period, or 7½ years where applicable, the district court decides that the patent is invalid, unenforceable, or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the 505(b)(2) application or ANDA may be approved on:

(A) The date on which the court enters judgment reflecting the decision; or

(B) The date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid, unenforceable, or not infringed.

(iii) *Appeal of Federal district court judgment of infringement.* If before the expiration of the 30-month period, or 7½ years where applicable, the district court decides that the patent has been

infringed, and if the judgment of the district court is appealed, the 505(b)(2) application or ANDA may be approved on:

(A) The date on which the mandate is issued by the court of appeals entering judgment that the patent is invalid, unenforceable, or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(B) The date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid, unenforceable, or not infringed.

(iv) *Affirmation or non-appeal of Federal district court judgment of infringement.* If before the expiration of the 30-month period, or 7½ years where applicable, the district court decides that the patent has been infringed, and if the judgment of the district court is not appealed or is affirmed, the 505(b)(2) application or ANDA may be approved no earlier than the date specified by the district court in an order under 35 U.S.C. 271(e)(4)(A).

(v) *Grant of preliminary injunction by Federal district court.* If before the expiration of the 30-month period, or 7½ years where applicable, the district court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug product until the court decides the issues of patent validity and infringement, and if the court later decides that:

(A) The patent is invalid, unenforceable, or not infringed, the 505(b)(2) application or ANDA may be approved as provided in paragraph (b)(3)(ii) of this section; or

(B) The patent is infringed, the 505(b)(2) application or ANDA may be approved as provided in paragraph (b)(3)(iii) or (iv) of this section, whichever is applicable.

(vi) *Written consent to approval by patent owner or exclusive patent licensee.* If before the expiration of the 30-month period, or 7½ years where applicable, the patent owner or the exclusive patent licensee (or their representatives) agrees in writing that the 505(b)(2) application or ANDA may be approved any time on or after the date of the consent, approval may be granted on or after that date.

(vii) *Court order terminating 30-month or 7½-year period.* If before the expiration of the 30-month period, or 7½ years where applicable, the court enters an order requiring the 30-month or 7½-year period to be terminated, the 505(b)(2) application or ANDA may be approved in accordance with the court's order.

(viii) *Court order of dismissal without a finding of infringement.* If before the expiration of the 30-month period, or 7½ years where applicable, the court(s) enter(s) an order of dismissal, with or without prejudice, without a finding of infringement in each pending suit for patent infringement brought within 45 days of receipt of the notice of paragraph IV certification sent by the 505(b)(2) or ANDA applicant, the 505(b)(2) application or ANDA may be approved on or after the date of the order.

(4) *Tentative approval.* FDA will issue a tentative approval letter when tentative approval is appropriate in accordance with this section. In order for a 505(b)(2) application or ANDA to be approved under paragraph (b)(3) of this section, the applicant must receive an approval letter from the Agency. Tentative approval of an NDA or ANDA does not constitute ''approval'' of an NDA or ANDA and cannot, absent an approval letter from the Agency, result in an approval under paragraph (b)(3) of this section.

(c) *Timing of approval of subsequent ANDA.* (1) If an ANDA contains a paragraph IV certification for a relevant patent and the ANDA is not that of a first applicant, the ANDA is regarded as the ANDA of a subsequent applicant. The ANDA of a subsequent applicant will not be approved during the period when any first applicant is eligible for 180-day exclusivity or during the 180-day exclusivity period of a first applicant. Any applicable 180-day exclusivity period cannot extend beyond the expiration of the patent upon which the 180-day exclusivity period was based.

(2) A first applicant must submit correspondence to its ANDA notifying FDA within 30 days of the date of its first commercial marketing of its drug product or the reference listed drug. If an applicant does not notify FDA, as required in this paragraph (c)(2), of this date, the date of first commercial marketing will be deemed to be the date of the drug product's approval.

(3) If FDA concludes that a first applicant is not actively pursuing approval of its ANDA, FDA may immediately approve an ANDA(s) of a subsequent applicant(s) if the ANDA(s) is otherwise eligible for approval.

(d) *Delay due to exclusivity.* The Agency will also delay the approval of a 505(b)(2) application or ANDA if delay is required by the exclusivity provisions in § 314.108; section 527 of the Federal Food, Drug, and Cosmetic Act and § 316.31 of this chapter; section 505A of the Federal Food, Drug, and Cosmetic Act; or section 505E of the Federal Food, Drug, and Cosmetic Act. When the approval of a 505(b)(2) application or ANDA is delayed under this section and § 314.108; section 527 of the Federal Food, Drug, and Cosmetic Act and § 316.31 of this chapter; section 505A of the Federal Food, Drug, and Cosmetic Act; or section 505E of the Federal Food, Drug, and Cosmetic Act, the 505(b)(2) application or ANDA will be approved on the latest of the days specified under this section and § 314.108; section 527 of the Federal Food, Drug, and Cosmetic Act and § 316.31 of this chapter; section 505A of the Federal Food, Drug, and Cosmetic Act; or section 505E of the Federal Food, Drug, and Cosmetic Act, as applicable.

(e) *Notification of court actions or written consent to approval.* (1) The applicant must submit the following information to FDA, as applicable:

(i) A copy of any judgment by the court (district court or mandate of the court of appeals) or settlement order or consent decree signed and entered by the court (district court or court of appeals) finding a patent described in paragraph (b)(3) of this section invalid, unenforceable, or not infringed, or finding the patent valid and infringed;

(ii) Written notification of whether or not any action by the court described in paragraph (e)(1)(i) of this section has been appealed within the time permitted for an appeal;

(iii) A copy of any order entered by the court terminating the 30-month or 7½-year period as described in paragraph (b)(3)(i), (ii), (vii), or (viii) of this section;

(iv) A copy of any written consent to approval by the patent owner or exclusive patent licensee described in paragraph (b)(3)(vi) of this section;

(v) A copy of any preliminary injunction described in paragraph (b)(3)(v) of this section, and a copy of any subsequent court order lifting the injunction; and

(vi) A copy of any court order pursuant to 35 U.S.C. 271(e)(4)(A) ordering that a 505(b)(2) application or ANDA may be approved no earlier than the date specified (irrespective of whether the injunction relates to a patent described in paragraph (b)(3) of this section).

(2) All information required by paragraph (e)(1) of this section must be sent to the applicant's NDA or ANDA, as appropriate, within 14 days of the date of entry by the court, the date of appeal or expiration of the time for appeal, or the date of written consent to approval, as applicable.

(f) *Forty-five day period after receipt of notice of paragraph IV certification*—(1) *Computation of 45-day time clock.* The 45-day clock described in paragraph (b)(3) of this section as to each recipient required to receive notice of paragraph IV certification under § 314.52 or § 314.95 begins on the day after the date of receipt of the applicant's notice of paragraph IV certification by the recipient. When the 45th day falls on Saturday, Sunday, or a Federal holiday, the 45th day will be the next day that is not a Saturday, Sunday, or a Federal holiday.

(2) *Notification of filing of legal action.* (i) The 505(b)(2) or ANDA applicant must notify FDA in writing within 14 days of the filing of any legal action filed within 45 days of receipt of the notice of paragraph IV certification by any recipient. A 505(b)(2) applicant must send the notification to its NDA. An ANDA applicant must send the notification to its ANDA. The notification to FDA of the legal action must include:

(A) The 505(b)(2) application or ANDA number.

(B) The name of the 505(b)(2) or ANDA applicant.

(C) The established name of the drug product or, if no established name exists, the name(s) of the active ingredient(s), the drug product's strength, and dosage form.

(D) A statement that an action for patent infringement, identified by court, case number, and the patent number(s) of the patent(s) at issue in the action, has been filed in an appropriate court on a specified date.

(ii) A patent owner or NDA holder (or its representative(s)) may also notify FDA of the filing of any legal action for patent infringement. The notice should contain the information and be sent to the offices or divisions described in paragraph (f)(2)(i) of this section.

(iii) If the 505(b)(2) or ANDA applicant, the patent owner(s), the NDA holder, or its representative(s) does not notify FDA in writing before the expiration of the 45-day time period or the completion of the Agency's review of the 505(b)(2) application or ANDA, whichever occurs later, that a legal action for patent infringement was filed within 45 days of receipt of the notice of paragraph IV certification, the 505(b)(2) application or ANDA may be approved upon expiration of the 45-day period (if the 505(b)(2) or ANDA applicant confirms that a legal action for patent infringement has not been filed) or upon completion of the Agency's review of the 505(b)(2) application or ANDA, whichever is later.

(3) *Waiver.* If the patent owner or NDA holder who is an exclusive patent licensee (or its representative(s)) waives its opportunity to file a legal action for patent infringement within 45 days of a receipt of the notice of certification and the patent owner or NDA holder who is an exclusive patent licensee (or its representative(s)) submits to FDA a valid waiver before the 45 days elapse, the 505(b)(2) application or ANDA may be approved upon completion of the Agency's review of the NDA or ANDA. FDA will only accept a waiver in the following form:

(*Name of patent owner or NDA holder who is an exclusive patent licensee or its representative(s)*) has received notice from (*name of applicant*) under (*section 505(b)(3) or 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act*) and does not intend to file an action for patent infringement against (*name of applicant*) concerning the drug (*name of drug*) before (*date on which 45 days elapse*). (*Name of patent owner or NDA holder who is an exclusive patent licensee*) waives the opportunity provided by (*section 505(c)(3)(C) or 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act*) and does not object to FDA's approval of (*name of applicant*)'s (*505(b)(2) application or ANDA*) for (*name of drug*) with an approval date on or after the date of this submission.

(g) *Conversion of approval to tentative approval.* If FDA issues an approval letter in error or a court enters an order requiring, in the case of an already approved 505(b)(2) application or ANDA, that the date of approval be delayed, FDA will convert the approval to a tentative approval if appropriate.

■ 19. Amend § 314.108 as follows:

■ a. In paragraph (a):

■ i. Revise the introductory text and the definitions of ''Approved under section 505(b)'', ''Essential to approval'', and ''New chemical entity'';

■ ii. Remove the definitions of ''Active moiety'', ''Date of approval'', and ''FDA''; and

■ iii. Add in alphabetical order the definition of ''Bioavailability study''; and

■ b. Revise the paragraph (b) heading and paragraphs (b)(2) through (5).

The revisions and addition read as follows:

§ 314.108 New drug product exclusivity.

(a) *Definitions.* The definitions in § 314.3 and the following definitions of terms apply to this section:

Approved under section 505(b) means an NDA submitted under section 505(b) and approved on or after October 10, 1962, or an application that was ''deemed approved'' under section 107(c)(2) of Public Law 87–781.

Bioavailability study means a study to determine the bioavailability or the pharmacokinetics of a drug.

* * * * *

Essential to approval means, with regard to an investigation, that there are no other data available that could support approval of the NDA.

New chemical entity means a drug that contains no active moiety that has been approved by FDA in any other NDA submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

(b) *Submission of and timing of approval of a 505(b)(2) application or ANDA.* * * *

(2) If a drug product that contains a new chemical entity was approved after September 24, 1984, in an NDA submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, no person may submit a 505(b)(2) application or ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act for a drug product that contains the same active moiety as in the new chemical entity for a period of 5 years from the date of approval of the first approved NDA, except that the 505(b)(2) application or ANDA may be submitted after 4 years if it contains a certification of patent invalidity or noninfringement described in § 314.50(i)(1)(i)(A)(*4*) or § 314.94(a)(12)(i)(A)(*4*).

(3) The approval of a 505(b)(2) application or ANDA described in paragraph (b)(2) of this section will occur as provided in § 314.107(b)(1) or (2), unless the owner of a patent that claims the drug, the patent owner's representative, or exclusive licensee brings suit for patent infringement against the applicant during the 1-year period beginning 48 months after the date of approval of the NDA for the new chemical entity and within 45 days after receipt of the notice described at § 314.52 or § 314.95, in which case, approval of the 505(b)(2) application or ANDA will occur as provided in § 314.107(b)(3).

(4) If an NDA:

(i) Was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act;

(ii) Was approved after September 24, 1984;

(iii) Was for a drug product that contains an active moiety that has been previously approved in another NDA under section 505(b) of the Federal Food, Drug, and Cosmetic Act; and

(iv) Contained reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the

applicant that were essential to approval of the application, for a period of 3 years after the date of approval of the application, the Agency will not approve a 505(b)(2) application or an ANDA for the conditions of approval of the NDA, or an ANDA submitted pursuant to an approved petition under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act that relies on the information supporting the conditions of approval of an original NDA.

(5) If a supplemental NDA:

(i) Was approved after September 24, 1984; and

(ii) Contained reports of new clinical investigations (other than bioavailability studies) that were conducted or sponsored by the applicant that were essential to approval of the supplemental NDA, for a period of 3 years after the date of approval of the supplemental application, the Agency will not approve a 505(b)(2) application or an ANDA for a change, or an ANDA submitted pursuant to an approved petition under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act that relies on the information supporting a change approved in the supplemental NDA.

■ 20. Amend § 314.125 as follows:

■ a. Remove the word ''application'' and add in its place ''NDA'' wherever it appears in paragraphs (a) introductory text, (a)(2), (b)(7), (9), (10), and (12), and (b)(14) through (18);

■ b. Remove the word ''act'' and add in its place ''Federal Food, Drug, and Cosmetic Act'' in paragraphs (a) introductory text and (b)(2), (11), and (18);

■ c. Revise the section heading and paragraph (b) introductory text; and

■ d. Add paragraph (b)(19).

The revisions and addition read as follows:

§ 314.125 Refusal to approve an NDA.

* * * * *

(b) FDA may refuse to approve an NDA for any of the following reasons, unless the requirement has been waived under § 314.90:

* * * * *

(19) The 505(b)(2) application failed to contain a patent certification or statement with respect to each listed patent for a drug product approved in an NDA that:

(i) Is pharmaceutically equivalent to the drug product for which the original 505(b)(2) application is submitted; and

(ii) Was approved before the original 505(b)(2) application was submitted.

* * * * *

■ 21. Amend § 314.127 as follows:

■ a. Remove the words ''abbreviated application'' and ''abbreviated new drug application'' wherever they appear and add in their place ''ANDA'' in paragraphs (a) introductory text, (a)(3) through (7), (a)(8)(ii)(A) introductory text, (a)(9) and (10), and (b);

■ b. Remove the word ''act'' wherever it appears and add in its place ''Federal Food, Drug, and Cosmetic Act'' in paragraphs (a)(3)(iii)(A)(*2*) and (a)(12);

■ c. Remove ''officer of employee'' and add in its place ''officer or employee'' in paragraph (b);

■ d. Revise the section heading and paragraphs (a) introductory text, (a)(2), (a)(8)(i) introductory text, and (a)(8)(ii)(B) and (C); and

■ e. Add paragraph (a)(14).

The revisions and addition read as follows:

§ 314.127 Refusal to approve an ANDA.

(a) FDA will refuse to approve an ANDA for a new drug under section 505(j) of the Federal Food, Drug, and Cosmetic Act for any of the following reasons, unless the requirement has been waived under § 314.99:

* * * * *

(2) Information submitted with the ANDA is insufficient to show that each of the proposed conditions of use has been previously approved for the listed drug referred to in the ANDA.

* * * * *

(8)(i) Information submitted in the ANDA or any other information available to FDA shows that:

* * * * *

(ii) * * *

(B) FDA will consider an inactive ingredient in, or the composition of, a drug product intended for parenteral use to be unsafe and will refuse to approve the ANDA unless it contains the same inactive ingredients, other than preservatives, buffers, and antioxidants, in the same concentration as the listed drug, and, if it differs from the listed drug in a preservative, buffer, or antioxidant, the ANDA contains sufficient information to demonstrate that the difference does not affect the safety or efficacy of the drug product.

(C) FDA will consider an inactive ingredient in, or the composition of, a drug product intended for ophthalmic or otic use unsafe and will refuse to approve the ANDA unless it contains the same inactive ingredients, other than preservatives, buffers, substances to adjust tonicity, or thickening agents, in the same concentration as the listed drug, and if it differs from the listed drug in a preservative, buffer, substance to adjust tonicity, or thickening agent, the ANDA contains sufficient information to demonstrate that the difference does not affect the safety or efficacy of the drug product and the labeling does not claim any therapeutic advantage over or difference from the listed drug.

* * * * *

(14) For an ANDA submitted pursuant to an approved petition under § 10.30 of this chapter and § 314.93, an NDA subsequently has been approved for the change described in the approved petition.

* * * * *

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

■ 22. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 371.

■ 23. Section 320.1 is revised to read as follows:

§ 320.1 Definitions.

The definitions contained in § 314.3 of this chapter apply to those terms when used in this part.

■ 24. Amend § 320.23 as follows:

■ a. Revise the last sentence in paragraph (a)(1);

■ b. Remove the word ''shall'' and add in its place the word ''must'' in paragraph (a)(2);

■ c. Redesignate paragraph (b) as paragraph (b)(1); and

■ d. Add paragraph (b)(2).

The revisions and additions read as follows:

§ 320.23 Basis for measuring in vivo bioavailability or demonstrating bioequivalence.

(a)(1) * * * For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

* * * * *

(b) * * *

(2) For drug products that are not intended to be absorbed into the bloodstream, bioequivalence may be demonstrated by scientifically valid methods that are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

Dated: September 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22690 Filed 10–5–16; 8:45 am]

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