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AAFA Statement on FDA Approval of Primatene Mist for Mild Asthma

November 9, 2018 – Washington, D.C. – People with asthma have more treatment choices than ever before, and the FDA recently announced approval for the readmittance of Primatene Mist – an over-the-counter (OTC) epinephrine inhaler. The Asthma and Allergy Foundation of America (AAFA) cautions patients to not stop their current asthma treatment nor start taking this OTC option without talking to their health care provider first.

AAFA President and CEO Kenneth Mendez states, “AAFA supports access to affordable treatment options for our community. However, it is unknown how the FDA’s approval of Primatene Mist may impact asthma outcomes. It is not currently a guidelines-based treatment. As with any medication and chronic condition, it’s important for people to consult with their doctor to make sure the medication is appropriate for them.”

Asthma is a chronic lung disease that causes airways to become inflamed, making it hard to breathe. Common symptoms include coughing, shortness of breath, wheezing and chest tightness. About 26 million Americans have asthma, including more than 18 million adults. There are about 3,600 annual deaths in the U.S. attributed to asthma. The annual combined societal cost of asthma is more than \$82 billion dollars.¹

As U.S. asthma rates increase, so do the costs for direct health care (hospitalizations and medication) and indirect health care (missed school and work days). An OTC option may help underserved populations with no other access to asthma treatment. But there are some risks in the use of Primatene Mist.

“We are concerned that this option will be misused as a replacement for a prescribed treatment plan – which it is not,” states Mitchell Grayson, MD, AAFA’s Medical-Scientific Council Chair. “We encourage patients to speak with their health care provider to determine if their asthma is under control and develop an action plan to help prevent asthma emergencies.”

¹ aafa.org/asthma-facts

Patients with moderate or severe persistent asthma should not depend on Primatene Mist. Work with your health care provider to follow an appropriate treatment plan tailored for you. Do not discontinue use of your current treatment until discussing with your physician. If you have a severe asthma attack, follow your asthma action plan and go to an emergency room immediately.

About AAFA

Celebrating 65 years of service, AAFA is the oldest and largest non-profit patient organization dedicated to improving the quality of life for people with asthma, allergies and related conditions through research, education, advocacy and support. AAFA provides practical information and community-based services through its digital communities and network of chapters and support groups. Through its [Kids with Food Allergies division](#), AAFA offers the most extensive online support community for families of children with food allergies. AAFA also helps consumers identify products suitable for those with asthma and allergies through the [asthma & allergy friendly® Certification Program](#). For more information, visit www.aafa.org.

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