ZANAMIVIR FACT SHEET FOR HEALTH CARE PROVIDERS

As you may already be aware, a public health emergency has been declared in the U.S. due to a current outbreak of swine influenza virus. You have been asked to give Relenza® (zanamivir), as appropriate, to people who may have been exposed to swine influenza A (H1N1). Zanamivir is approved by the U.S. Food and Drug Administration (FDA) for treatment of influenza in patients 7 years of age and older who have been symptomatic for no more than 2 days, and for prophylaxis of influenza in patients 5 years of age and older.* The FDA-approved package insert on zanamivir can be found via Drugs@FDA on www.fda.gov/cder.

Who should not take Zanamivir?
Patients with a history of severe allergic reaction to zanamivir or lactose, or have an underlying airway disease should not take zanamivir. Zanamivir should only be used for treatment of persons aged 7 years and older and for prevention in persons aged 5 years and older. It should not be used for prevention of flu in nursing home patients.

What is the dose of Zanamivir?
- **For Treatment**: 10 mg (2 inhalations) twice daily for 5 days
- **For Prevention:** Household Setting: 10 mg (2 inhalations) once daily for 10 days
  Community Outbreaks: 10 mg (2 inhalations) once daily for 28 days

The dose should be given at approximately the same time each day.

Zanamivir will be supplied in the manufacturer's packaging. Zanamivir is packaged in a medicine disk called a Rotadisk® and is inhaled by mouth using a delivery device called a Diskhaler®. Each Rotadisk® contains 4 blisters. Each blister contains 5 mg of active drug and 20 mg of lactose powder (which contains milk proteins). Each packaged box of zanamivir contains 5 Rotadisks® (total of 10 doses) and a Diskhaler® inhalation device.

Zanamivir should be given to children only under adult supervision and instruction, and the supervising adult should first be instructed by a healthcare professional. Instructions should include a demonstration whenever possible.

What are the possible serious side effects of Zanamivir?
- Some patients have had bronchospasm or serious breathing problems when they used zanamivir. Zanamivir is not recommended for people with chronic respiratory disease such as asthma or chronic obstructive pulmonary disease.
- Patients with lung disease should have a fast-acting inhaled bronchodilator available while being treated with zanamivir. Bronchodilators should be used prior to administration of zanamivir.
- People with the flu, particularly children and adolescents, may be at an increased risk of seizures, confusion, or abnormal behavior early in their illness. These events may occur after beginning zanamivir or may occur when flu is not treated. These events are uncommon but may result in accidental injury to the patient. Therefore, patients should be observed for signs of unusual behavior.
- Zanamivir was not effective in reducing the chance of getting the flu in 2 studies in nursing home patients.
- Patients should be instructed to stop taking zanamivir if they experience signs or symptoms of an allergic reaction.

Refer to the Package Insert for more safety information.
Make available to recipients the information in the "Zanamivir Summary Fact Sheet for Patients and Parents."

Reporting And Monitoring Adverse Events
Health care providers and recipients that experience adverse events or medication errors are encouraged to report to MedWatch at www.fda.gov/medwatch, by submitting a MedWatch Form 3500 (available at http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf) or by calling 1-800-FDA-1088.

*Certain aspects of this emergency use are not part of the approved drug applications. However, the FDA Commissioner has authorized the emergency use of zanamivir. Additional information can be found on: www.cdc.gov/swineflu.