



MyFluVaccine Update
 To: Valued FFF Customer
 From: FFF Enterprises
 Date: Friday, August 22, 2014

2014-15 INFLUENZA VACCINE PRODUCTS
 Important News! Flu Vaccine Delivery Update

FFF Enterprises Shipping Status of Influenza Vaccine Products

Novartis Vaccines plans for delivery of at least 30 million doses of Flucelvax and Fluvirin for the 2014-2015 Season. Shipments of Flucelvax from Novartis' newly licensed U.S. plant have begun early, (in the mid-July time frame) and FFF is running ahead of scheduled deliveries for Flucelvax. Also, Flucelvax now has price parity with Fluvirin PFS and is currently readily available for delivery within a few days lead time for new orders.

Novartis has also started shipments to FFF of Fluvirin prefilled syringes and Fluvirin multi-dose vials, and shipments to date have been lighter than expected with a slight gap in deliveries that may shift delivery expectations 1 to 2 weeks behind original delivery date estimates. This is due to a slight backlog of CBER lot approvals related to a relocation (move) of some of the CBER offices used for lot protocol testing.

See CBER Move

<http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm385240.htm>

Sanofi Pasteur started shipments to FFF for 4 of their 8 Fluzone vaccine product images. Deliveries of these 4 Fluzone products (listed below with August start dates) are running about 1 to 2 weeks behind original delivery schedules at this time. The four remaining Fluzone products, that have not yet started shipping to FFF, are listed in the grid below (with September start dates). Sanofi Pasteur has made FFF aware that there will be a shift in the delivery expectations for these products and is estimating a delay from the original schedule of several weeks (making delivery closer to the end of September).

Sanofi Pasteur has provided FFF with the following guideline for the start of shipping to FFF of each item as listed below.

Fluzone Shipping Timeline

Product	Shipping Begins
Fluzone High-Dose vaccine, 0.5 mL prefilled syringe	August
Fluzone Quadrivalent vaccine, 0.25 mL (pediatric dose) prefilled syringe	August
Fluzone Quadrivalent vaccine, 0.5 mL prefilled syringe	August
Fluzone Quadrivalent vaccine, 0.5 mL single-dose vial	August
Fluzone vaccine, 0.5 mL prefilled syringe	September
Fluzone vaccine, 5 mL multi-dose vial	September
Fluzone Quadrivalent vaccine, 5 mL multi-dose vial	September
Fluzone Intradermal vaccine, 0.1 mL microinjection	September

GlaxoSmithKline (GSK) has started shipments of their Fluarix Quadrivalent product to FFF and all shipments of Fluarix Quadrivalent vaccine are running on time to date. GSK's first shipment of FluLaval trivalent vaccine is expected to arrive at FFF the week of August 25th. Currently, FluLaval trivalent shipments are estimated running about 3 to 4 weeks behind schedule. FluLaval Quadrivalent vaccine has not yet started shipping to FFF, and GSK has reported that delays for both FluLaval trivalent and FluLaval Quadrivalent products are due to the FDA issues at their Canadian plant where these vaccines are produced. GSK has provided published information regarding these delays for these products, which can be found at the following link - <http://www.fffenterprises.com/assets/downloads/GSK%20FluLaval%20Supply%20Update%20June%2024%202014.pdf>

We expect GSK to start initial shipments of FluLaval Quadrivalent shortly and FFF will let customers know as soon as GSK starts shipments of FluLaval Quadrivalent vaccines to FFF.

bioCSL has started shipments of both Afluria multi-dose vials and Afluria prefilled syringes to FFF. Shipments of multi-dose vials have been lighter than expected, leading to a slight gap in our deliveries that may delay vial shipments 1 to 2 weeks from the original anticipated delivery schedule. Shipments of Afluria prefilled syringes are running on time. Also, FFF is continuing to take orders for Afluria prefilled syringes as long as limited supplies are available.

MedImmune shipments of FluMist usually start to arrive at FFF Enterprises each year in the 3rd to 4th week of July. However, at this time MedImmune has not yet started any shipments of FluMist Quadrivalent Live Intranasal Vaccine to the marketplace, and has announced that they are currently completing internal work required for their first release of product. Expect first shipments to begin arriving at FFF sometime next week. At this time, we are waiting on daily updates from MedImmune and will let customers know as soon as we start to receive our first shipments of FluMist. It is anticipated that shipments of FluMist will be at least 3 to 4 weeks behind the original planned scheduled delivery dates.

Copies of the MedImmune Dear Health Care Supply Letter are available upon request. Please contact your FFF representative or Wow! Customer Care at **(800) 843-7477**.

Protein Sciences expects to start shipments of Flublok as anticipated, beginning approximately the week of September 22. They have received their annual formulation and strain change approval from the FDA and have also recently received an additional FDA approval for this season to allow an extended shelf life for Flublok (through a 6-month expiration dating period), a change from last season's 16-week shelf life for Flublok. FFF will announce when the first shipments of Flublok are received at FFF and shipping of Flublok to the market begins.

View the Protein Sciences' press release for extended expiration - <http://www.fffenterprises.com/assets/downloads/ProtienScience%20August%202014.pdf>

2014-15 Updates of ACIP Prevention and Control of Seasonal Influenza with Vaccines

Influenza Vaccine Composition for the 2014-15 Season

U.S licensed vaccines will contain the same vaccine virus strains as those in the 2013-14 vaccine. Trivalent influenza vaccines will contain hemagglutinin (HA) derived from an A/California/7/2009 (H1N1)-like virus, an A/Texas/50/2012 (H3N2)-like virus, and a B/Massachusetts/2/2012-like (Yamagata lineage) virus. Quadrivalent influenza vaccines will contain these antigens, and also a B/Brisbane/60/2008-like (Victoria lineage) virus.

Vaccine Dose Considerations for Children Aged 6 Months through 8 Years Children aged 6 months through 8 years require 2 doses of influenza vaccine administered \geq 4 weeks apart during their first season of vaccination. However, as the strains contained in this year's vaccine are identical to those contained in the 2013-14 vaccines, this season only 1 dose is required for any child aged 6 months through 8 years who previously received \geq 1 dose of 2013-14 seasonal influenza vaccine.

Preference for the Use, when Immediately Available

Live attenuated influenza vaccine (LAIV) for healthy children aged 2 through 8 years, to be implemented as feasible for the 2014-15 season but no later than the 2015-16 season.

See the full ACIP 2014-15 Seasonal Influenza Vaccine Recommendations -
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6332a3.htm?s_cid=mm6332a3_e

Please contact your FFF representative or Wow! Customer Care at **(800) 843-7477** if you have any questions.

Sincerely,

FFF Enterprises