September 10, 2013

Shawn Brown

Dear Mr. Brown:

This is in response to your letter to the U.S. Food and Drug Administration (FDA) requesting information on jet injectors.

According to FDA’s updated communication on the use of jet injectors to deliver vaccines, data to support their safety and effectiveness have not been submitted to the FDA for evaluation. However, the FDA has not “banned” them.

I am enclosing this recent updated communication. If after reading our information you have further questions, please refer to the “Contact Information” listed on this document.

I hope this information is helpful.

Sincerely,

Bonnie J. Alderton
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FDA Updated Communication on Use of Jet Injectors with Inactivated Influenza Vaccines

Date Issued: October 26, 2011

Audience: Health care professionals who administer inactivated influenza vaccines

Purpose: The Food and Drug Administration (FDA) is recommending that health care professionals use a sterile needle and syringe to administer inactivated influenza vaccines.

Summary of the Issue

FDA has recently received questions regarding the use of jet injector devices to administer inactivated influenza vaccines. Inactivated influenza vaccines that are approved by the FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration. The FDA is clarifying its October 21, 2011, communication to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector. FDA's recommendation to administer inactivated influenza vaccines using a sterile needle and syringe is based on studies submitted to FDA in support of the vaccine approvals.

- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by the FDA for administration by jet injector.

Background Information

FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulating biological products, including vaccines. When the FDA approves a vaccine, the approval is based on scientific information demonstrating the safety and effectiveness of that vaccine in a given population (e.g., children, adults or the elderly), using a specific dose, schedule and method/route of administration. Changes in the dose, route and/or method of administration have the potential to impact the effectiveness and the safety profile of a vaccine.

Inactivated influenza vaccines have been approved only for administration by needle injection. The clinical studies submitted in support of approval of the inactivated influenza vaccines did not include evaluation of safety and effectiveness following administration by jet injector. If a manufacturer wants to include the jet injector as a method of vaccine administration in its vaccine labeling, the safety and effectiveness data to support administration of the vaccine using this delivery method must be submitted to FDA for evaluation and approval.

FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating medical devices, including those used to administer drugs and biologics (such as vaccines). Jet Injectors that have been cleared by FDA to deliver medications and vaccines should be used to deliver only those medications and vaccines that have been approved and specifically labeled for use with a jet injector.

Recommendations/Actions

FDA recommends using a sterile needle and syringe to administer inactivated influenza vaccines.

If a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling.

Based on limited information from recent publications using currently licensed inactivated influenza vaccines, FDA and the Centers for Disease Control and Prevention (CDC) believe that it is not necessary for people who received their influenza vaccine via jet injector to be re-vaccinated.
Questions and Answers

Are there data on the safety and effectiveness of inactivated influenza vaccine administered using a jet injector?

Data to support the safety or effectiveness of inactivated influenza vaccines delivered by jet injector have not been submitted to FDA for evaluation. Data with currently licensed inactivated influenza vaccines are limited. FDA is aware of a study conducted in healthy young adults published in 2001 (Jackson, et al. Vaccine 2001) that reported that the immune response to an inactivated influenza vaccine administered with a jet injector was comparable to that following administration using a needle and syringe. Those people vaccinated with the jet injector in this study tended to have more pain and redness at the injection site. Another study in young healthy adults by Simon, et al (Vaccine, 2011) reported that the immune response was similar following an influenza vaccine administered by syringe or jet injector; however, redness and swelling occurred more frequently in those vaccinated with the jet injector. These studies did not include infants, children or older adults.

If a jet injector has been cleared by FDA for administration of vaccines, does that mean it can be used to administer inactivated influenza vaccines?

FDA has not determined the safety and effectiveness of inactivated influenza vaccines when administered using jet injectors. A jet injector subjects the vaccine to a different pressure than it would receive during administration by sterile needle and syringe and as a result the effectiveness and the safety profile of the injected vaccine may be altered. Therefore, jet injectors that have been cleared by FDA to deliver medications and vaccines should be used to deliver only those products that have been specifically labeled for use with a jet injector, as this means that clinical studies that evaluated safety and effectiveness have been submitted in a drug or biologic application for review and approval.

Does FDA recommend that inactivated influenza vaccinations be given by jet injector?

FDA recommends that the inactivated influenza vaccines be given with a needle and syringe, unless the FDA vaccine labeling specifies otherwise. If a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling.

What should I do if I got an influenza vaccine using a needle-free jet injector? Do I need to get vaccinated again?

Based on limited information from recent publications using currently licensed inactivated influenza vaccines, FDA and CDC believe that people who got their influenza vaccine via jet injector do not need to be re-vaccinated.

Contact Information

If you have questions about this communication, please contact CBER’s Office of Communication, Outreach and Development by phone at 1-800-835-4709, or email at ocd@fda.hhs.gov.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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For Government For Press
Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

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Aug. 18, 2013

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Center for Devices and Radiological Health,

I am doing research on the jet injector vaccination device. I have been grossly misinformed. I thought the jet injector was still banned. I have two questions for your agency.

1) Does your office recognize that the older models of jet injectors pose a health hazard in that it can cross-contaminate blood? If so, do you have any memoranda documenting this?

2) Do you have any research that shows the current jet injectors being used do not cross-contaminate blood?

I greatly thank you for your assistance.

Sincerely,