FDA Emergency Use Authorization Request for Intranasal Influenza Vaccine Delivery

(Prepared and Filed By D. Foggia (UNI Product Invention Developer) August 2009)

Summary of Recommended Data to Support a Request for Consideration:

For FDA to evaluate a request for consideration for an EUA, the Agency recommends that the following information be submitted:

1. a description of the product and its intended use (e.g., identification of the serious or life-threatening disease or condition for which the product may be effective);
2. identification and an explanation of what unmet need(s) would be addressed by issuance of the EUA;
3. a description of the product's approval or clearance status, if any, under the FD&C Act or licensure status under the PHS Act, and whether the product is under an investigational application (e.g., whether the product is unapproved or whether it is approved but the EUA is for an unapproved use; whether an IND or IDE is in effect or has been submitted); whether the product is licensed for either the proposed or another use in a foreign country; information on the use of the medical product by either a foreign country or an international mutual defense organization such as NATO;
4. a list of each site where the product, if authorized, would be (or was) manufactured and the Good Manufacturing Practices (GMP) status of the manufacturer;
5. identification of any approved alternative products, including their availability and adequacy for the proposed use (if known);
6. available safety and effectiveness information for the product;
7. a discussion of risks and benefits;
8. a description of the information for health care providers or authorized dispensers and recipients of the product, (e.g., two separate “Fact Sheets”), and the feasibility of providing such information to health care providers or authorized dispensers and recipients in emergency situations;
9. information on chemistry, manufacturing, and controls;
10. instructions for use of the EUA product (e.g., if follow-up treatment is required); and
11. proposed labeling (if applicable).
12. right of reference (if applicable).

Data to Support an EUA Request for Consideration

1. Due to the current epidemic of the A (H1N1) virus and the potential mutations and spreading of other influenza viruses worldwide, combined with a consideration of the currently used influenza delivery technologies, an unapproved use for an approved product is hereby requested. The approved product is referred to as the Undetectable Nasal Insert (UNI) and is identified by FDA number C070237 which was approved on October 1, 2007. The unapproved use of the device would be for the intranasal delivery of influenza vaccines. Use of the UNI Device for the intranasal delivery of influenza vaccines may be effective at increasing the overall safety, convenience, effectiveness and use of these vaccines.

2. There are major unmet safety needs associated with the use of current technologies (i.e. syringe technology) for the delivery of influenza vaccines that the UNI device could overcome. It is proposed that the device would be a far safer choice for the intranasal delivery of influenza vaccines for two primary reasons:

A. Vaccine flow rate from the device can be slowed. For the delivery of influenza vaccines the UNI Device would not operate on the principle of rapidly flooding those vaccines into the human body. Rather, each pad section of the device would be designed to carry a precise dose of vaccine and slowly release it into the nasal passages over an extended period of time.

With a slow controlled release of the vaccine, the device may be effective at reducing the risk of mild to severe nasal irritation, systemic allergic reaction or potential permanent systemic damage.

B. Vaccine flow from the device can be stopped at any time. Unlike any other known intranasal technology, the UNI device would allow for vaccine flow to be ceased at the onset of significant nasal irritation or allergic reaction. The administering healthcare professional or individual patient could immediately remove the device from the nose at the presence of serious irritation or allergic reaction. Since the device would operate on the principle of slow controlled release of vaccines into the nasal passages, removal of the device from the nose would discontinue further vaccine flow. The existing intranasal technology currently available (FluMist) rapidly floods vaccines into the body which negates any possibility of retrieving the vaccines or ceasing further flow in the event of mild or severe nasal irritation or allergic reaction.

There are also secondary unmet safety needs that the UNI Device could also address as follows:

C. Unlike FluMist, the device could not be accidentally sprayed onto the patient's face or into the patient's eyes

D. Device could not be accidentally sprayed onto healthcare staff

E. Device is soft and pliable rather than rigid and sharply pointed (FluMist) which would be a safer device while being used in close proximity to a patient's face and eyes

F. In-use or discarded device is not pointed and could not harm healthcare staff or trash handlers

G. Unlike FluMist, the device does not resemble a syringe and this fact may be effective at reducing the overall stress level in patients

H. As opposed to FluMist, both sides of the nose would be treated with the vaccine simultaneously thus avoiding an uneasy pause between sprays

I. Patients themselves could safely self-administer the device in front of healthcare staff which would tend to reduce stress to both patients and staff

J. Patients could safely remove the device from their nose after use and dispose of in the trash

There are also other additional unmet needs that the UNI Device may be effective at addressing which are:

K. Granting use of the device would provide an additional alternative delivery device to dangerous invasive injectables

L. Since the device could increase nasal residence time and potential bio-adhesion, it may be effective at producing a strong immune response with less vaccine required than current syringe technologies

M. Due to the size of the device it would likely produce a fraction of the plastic waste of current syringe technologies

N. Through the combination of all of the above mentioned potential benefits of the device it may be effective at reducing the negative stigma that haunts vaccines to this day and instead raise public acceptance of vaccine use

3. For the indication of odor control, the FDA has determined that the Undetectable Nasal Insert does not meet the definition of a “device” as defined in section 201(h) of the Act (See attached FDA response letter).

4. Not Applicable. Device has been hand-made only. (However, a product development company in Atlanta analyzed the product extensively and could provide the information to speed development time, if necessary).

5. FluMist

6. Not Applicable. Device has not been tested for the delivery of vaccines.

7. It is proposed that the physical design of the device would remain essentially the same for vaccine delivery as with the current approved use of odor control. The primary difference would be that the device would function to *deliver* influenza vaccines at a slow controlled rate as opposed to *containing* and not releasing an odor control substance. By combining a slower controlled vaccine release with the enhanced ability to remove the device and cease further vaccine flow, it is proposed that the UNI Device would be a significantly safer intranasal vaccine delivery device.

8. Unknown

9. The device would likely be made of polyester pads sonically welded to transparent polyester monofilament.

10. Instructions for Use:

1.) Clean hands thoroughly with soap and water

2.) Open foil pouch by tearing across on the dotted line

3.) Remove Nasal Insert and place one pad through each nostril of the nose

4.) Position each pad toward the inside ceiling of the nose to allow for airflow

5.) Re-wash hands thoroughly with soap and water

6.) After use, remove by exhaling air through the nose into a clean tissue or napkin and dispose of in a trash receptacle.

11. Unknown

12. Unknown