FDA Emergency Use Authorization Request for Intranasal Pathogen Destroyer

(Prepared By D. Foggia (UNI Product Invention Developer) June 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

(Pre-Draft EUA for Intranasal Pathogen Destroyer)

1. Due to the epidemic of the A (H1N1) virus, its rapid spread and potential mutation, 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.

For the unapproved use it is proposed that by adding the proper solution of Chlorhexidine Gluconate (CHG) to the UNI Device that the combination of the two may be effective at killing or deactivating A (H1N1) viruses attempting to transit the nasal route in humans. In this use, the device would function primarily as a fibrous containment mass (pad) for the CHG. It would not be the function of the UNI Device to deliver the CHG to the nasal mucosa or systemically throughout the body. Each insertable pad section of the UNI Device would be manufactured as a fibrous body coated with CHG. Each of these bodies would then be inserted just inside the nostril to generally occupy the area of the nasal vestibule or potentially fill the nasal passage. The UNI Device positioned in this way may be effective at killing A (H1N1) viruses attempting to enter the nasal route of uninfected people, and conversely, may be effective at killing viruses attempting to leave infected people via normal exhaling or nasal mucus discharge. The device can be worn comfortably underneath all forms of facial protection for long periods of time (hours) and its position within the nose can be effectively adjusted without removal of the outer facial protection.

When the person is ready to remove the device they can simply ‘blow the nose’ into a clean napkin or facial tissue for sanitary removal and disposal.

2A. It has been observed that the primary defense against the spread of the A (H1N1) and other influenza viruses of the past has been the issuance to the public of standard facial masks. Since the size and shape of the human face differs so widely and since the public is not accustom to using these masks, it is contended that they invariably leak due to improper fit and improper use or installation (it is also recognized that N95 respiratory masks do not offer protection to children)

- One size mask does not fit all and these masks do not form an airtight seal to the skin around their perimeters. Under close examination, there are always gaps between the skin and mask in areas around the perimeter which allows outside air to freely enter under the mask

- The public is simply not used to wearing facial masks. As a result, it should be expected that many people will use these masks improperly which increases potential leakage. For example, some people may choose to only cover their mouth with the mask and leave their nose to the open air. Many people will experience a general claustrophobic reaction to wearing these masks and will be forced to open them frequently to get more airflow. Others will simply install the mask in an awkward or loose fashion causing extensive leakage to occur.

There is an unmet need to provide the public, children and healthcare staff with a secondary or additional form of protection that can be used under standard facial masks. If an EUA were granted for this use of the device, the product may be effective at killing or deactivating A (H1N1) viruses and other pathogens entering the nose while wearing facial protection or not.

2B. The installed UNI Device treated with CHG may be effective at reducing the number of live or activated A (H1N1) viruses and other pathogens leaving infected persons and entering into a given environment. It is well known that live influenza viruses can be found in the nasal discharge of infected persons. If CHG were contained on the UNI device and positioned inside the nose, live viruses that made contact with the CHG would likely be deactivated or destroyed. This result would be valuable to any environment, but especially important to healthcare facilities trying to reduce the total number of pathogens entering the facility.

2C. When people return to the privacy of their own homes during an epidemic, it can be expected that most will tend to remove protective facial masks to increase airflow and gain relief from mask discomfort. However, there may indeed be some contamination of the virus within the home for many reasons. Viruses may enter the home on clothing, from opening doors or windows or from family members who begin to develop symptoms of infection. By making the UNI device available, people at home would have access to an additional convenient device that they could use while not using the protective facial mask. Again, as generally stated above, the CHG treated UNI device might be effective at destroying or deactivating both viruses attempting to enter the noses of uninfected family members or attempting to leave the noses of infected family members into the home environment. Additionally, due to the comfort of the UNI device, most people could sleep with the device in place for extended overnight protection (8-10 hours) without significant complication.

2D. In the absence of a standard facial mask it is generally understood that infection by the A (H1N1) virus occurs in part when people touch contaminated surfaces in an infected environment and then inadvertently scratch or pick at the nose without properly sanitizing the hands with soap and water. In instances where a facial mask is not being used or is unavailable, general use of CHG treated UNI device may be effective at reminding the user to avoid hand to nose contact. This is due to the fact that although the device is quite comfortable to wear, it can still usually be felt inside the nose. People could be instructed in the Directions for Use to use the device as a reminder to avoid hand to nose contact until or unless the hands are properly sanitized. The device may also be effective as a physical obstruction against picking the nose since the pad sections are generally positioned just inside the nostril and make the act awkward.

2E. The CHG treated UNI device may be effective at reducing the overall occurrence of coughing and sneezing during this and other epidemics. By additionally treating the device with a safe GRAS substance such as diluted white camphor oil, the device may be effective at reducing overall coughing without the need of delivering cold/cough medications to the body. The device simply treated with CHG may be effective at reducing the number of times a person sneezes. This is mainly due to the physical design of the device and the physical location where it is positioned inside the nose. However, it is also likely that an additional GRAS substance could be incorporated on the device to reduce sneezing.

2F. Many people in society will ultimately choose not to wear facial protection masks due to general facial irritation, feelings of claustrophobia, lack of mask access or short supply, rebelliousness and various other reasons. Due to this occurrence in every society, it is felt that the use of the CHG treated UNI device could offer some alternative protection to this group. People experiencing facial irritation or claustrophobia would likely be attracted toward using the UNI device to potentially provide at least some protection against the virus. The device would offer far more comfort than a facial mask with the increased ability to breathe. Rebellious youth might likely be enticed to use the UNI product extensively because of its discreet nature. It could also be scented with various flavors that would appeal to youth. Where protective masks were unavailable or in short supply such as in poorer countries, there could at least be supplies of CHG treated UNI devices on hand. Each packaged device would be far smaller and thus easier to store and transport than facial protection masks. The devices would also be comparatively far cheaper to produce and supply.

2G. There is always a need worldwide to think of ways to better protect healthcare professionals in healthcare facilities and in the field. By granting use of the (CHG treated) UNI Device for the proposed use while also allowing combined incorporation of a GRAS odor control substance, the device may be effective at simultaneously protecting healthcare professionals from both foul odors and dangerous pathogens. The device could also offer the same protection to patients and visitors to healthcare facilities.

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 513g response letter).

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

5. There are no known alternative products that can be directly compared to the UNI product for the proposed use.

6. It is proposed that the safety of the UNI product would be very similar for the current proposed use as with the existing FDA approved use of odor control. As with odor control, this new proposed use of the UNI Device would involve containment of the CHG for use inside the nasal cavity. Once positioned there, the CHG would remain largely contained on the insert pads where it would collect and destroy passing viruses. The function of the UNI Device would not be to deliver CHG to the nasal mucosa or systemically to the body.

7. It is proposed that the impregnation of a 2.25% Chlorhexidine gluconate solution on the UNI product will not cause significant nasal irritation nor pose a significant threat to human life. This is due to the fact that the device will primarily act to carry in and contain the CHG on the pad sections of the device. It will not be the function of the device to deliver or release the CHG into the nasal passages which reduces the chance of nasal irritation or significant systemic delivery of the drug. In the event of any nasal irritation from the CHG the user can simply remove the device from the nose and discontinue use.

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